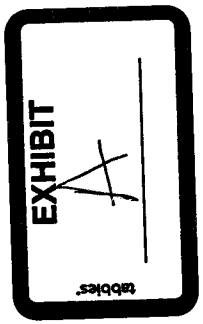
Case:d-1-gn-13-003530 with (22) documents

Filed Date	Category	Description	Additional Info
10/10/20...	PET-PL ...	ORIGINAL PETITION/APPLICATION	PLAINTIFF'S ORIGINAL PETITION
3/25/2014	MOTION ...	MTN:OTHER MOTION	MOTION FOR EXTENSION OF TIME FOR PETITION TO REMAIN UNDER SE AL AND FOR THE STATE TO CONSIDER INTER...
3/25/2014	ORD ...	ORD:OTHER ORDER	ORDER GRANTING EXTENSION OF TIME FOR PETITION TO REMAIN UNDE R SEAL AND FOR THE STATE TO CONSIDER I...
5/8/2014	NOTICE ...	NTC:OTHER NOTICE	NOTICE OF ELECTION OF ALTERNATE REMEDY AGAINST CERTAIN DEFEN DANTS AND AGREED MOTION FOR PARTIALL...
5/14/2014	MOTION ...	MTN:OTHER MOTION	UNOPPOSED EX PARTE MOTION OF THE STATE OF TEXAS TO PARTIALLY LIFT SEAL (UNDER SEAL)
5/14/2014	ORD ...	ORD:OTHER ORDER	ORDER GRANTING UNOPPOSED EX PARTE MOTION OF THE STATE OF TEX AS TO PARTIALLY LIFT SEAL (UNDER SEAL) ...
8/12/2014	ORD ...	ORD:OTHER ORDER	UNOPPOSED EX PARTE APPLICATION OF THE STATE OF TEXAS TO PART IALLY LIFT SEAL
8/12/2014	MOTION ...	MTN:OTHER MOTION	UNOPPOSED EX PARTE APPLICATION OF THE STATE OF TEXAS TO PART IALLY LIFT SEAL
9/10/2014	ORD ...	ORD:OTHER ORDER	ORDER GRANTING MOTION TO EXTEND SEAL AND TIME FOR THE STATE TO CONSIDER INTERVENTION ...
9/10/2014	MOTION ...	MTN:OTHER MOTION	MOTION TO EXTEND SEAL AND TIME FOR THE STATE TO CONSIDER INTERVENTION
10/1/2014	NOTICE ...	NTC:OTHER NOTICE	STATE OF TEXAS' NOTICE OF INTERVENTION
10/7/2014	PET-PL ...	!AMENDED/COUNTER/CROSS	PLAINTIFFS' FIRST AMENDED PETITION
10/8/2014	ORD ...	!ORD:OTHER ORDER	AGREED ORDER LIFTING AND REMOVING SEAL AND ALLOWING SERVICE OF PROCESS UPON DEFENDANTS ...
10/8/2014	MOTION ...	MTN:OTHER MOTION	STATE OF TEXAS' MOTION TO UNSEAL
10/8/2014	ORD ...	ORD:OTHER ORDER	AGREED ORDER LIFTING AND REMOVING SEAL AND ALLOWING SERVICE OF PROCESS UPON DEFENDANTS ...
10/15/20...	OTHER ...	OTHER FILING	LETTER
10/30/20...	OTHER ...	RULE 11 AGREEMENT	RULE 11 AGREEMENT
11/14/20...	PET-PL ...	AMENDED PETITION/COUNTER/CROSS	PLAINTIFF'S SECOND AMENDED PETITION
11/14/20...	OTHER ...	OTHER FILING	CITATION REQUEST
11/20/2014	MOTION	MTN:MOTION TO RETAIN	PLAINTIFFS' MOTION TO RETAIN AND MEMORANDUM OF FACTS AND LAW IN SUPPORT OF MOTION TO RETAIN (FORWARDED TO THE COURT ADMI NISTRATOR'S OFFICE)
11/24/20...	OTHER ...	OTHER FILING	LETTER REGARDING DISMISSAL DOCKET
12/2/2014	ORD ...	ORD:RETAIN	ORDER GRANTING MOTION TO RETAIN



CAUSE NO. D-1-GN-13-003530

THE STATE OF TEXAS, *ex rel.* **ALLISON ZAYAS and TRACY MIKSELL-BRANCH,**	§	**IN THE DISTRICT COURT**
Plaintiffs,	§	**353d JUDICIAL DISTRICT**
v.	§	
ASTRAZENECA, L.P., ASTRAZENECA PHARMACEUTICALS, L.P., ASTRAZENECA BIOPHARMACEUTICALS, INC., and ASTRAZENECA PLC,	§	**TRAVIS COUNTY, TEXAS**
Defendants.	§	**FILED UNDER SEAL**

PLAINTIFFS' FIRST AMENDED PETITION

The State of Texas, by and through the Attorney General of Texas, Greg Abbott, ("the State") and Private Person Plaintiff/Relators Tracy Miksell-Branch ("Relator Miksell-Branch") and Allison Zayas ("Relator Zayas") (collectively, "Relators") bring this law enforcement action pursuant to the Texas Medicaid Fraud Prevention Act ("TMFPA"), TEX. HUM. RES. CODE Chapter 36, and common law. Plaintiffs, the State and Relators, file this First Amended Petition (the "Petition") and would respectfully show the Court as follows:

I. DISCOVERY CONTROL PLAN

1. Discovery is intended to be conducted under Level 3 of Rule 190, Texas Rules of Civil Procedure.

II. PRELIMINARY STATEMENT AND NATURE OF THIS ACTION

2. This is a law enforcement action under the TMFPA and common law to recover taxpayer dollars spent as a result of AstraZeneca's fraudulent conduct. Specifically, AstraZeneca

targeted Texas Medicaid with a fraudulent marketing scheme for its expensive and powerful atypical antipsychotic drugs Seroquel (herein "Seroquel IR") and Seroquel XR. Under this scheme, AstraZeneca disseminated false and/or misleading messages during thousands of sales calls to doctors and other healthcare practitioners who were enrolled Texas Medicaid providers, including: 1) false and/or misleading messaging relating to the drugs' efficacy in unapproved conditions; 2) false and/or misleading messaging intended to downplay certain side effects; and 3) false and/or misleading messaging concealing the potent nature of these drugs. Additionally, AstraZeneca promoted Seroquel IR and Seroquel XR for unapproved use in the vulnerable pediatric population. Further, as part of their marketing plan to drive sales for Seroquel IR and Seroquel XR, AstraZeneca unduly influenced and improperly exploited Texas state officials to facilitate their misrepresentations. This illegal conduct caused Seroquel IR and Seroquel XR to be in violation of federal and state law, and rendered false AstraZeneca's sworn certifications of compliance to Texas Medicaid, which are required for drugs to be listed on the Texas Medicaid formulary. As a result, AstraZeneca obtained the benefit of virtually unfettered Medicaid reimbursements for Seroquel IR and Seroquel XR on the basis of fraudulent and unlawful misrepresentations, and in so doing, AstraZeneca violated the TMFPA and Texas common law.

III. THE PARTIES

A. The Plaintiffs

3. The Plaintiffs are the State of Texas, by and through the Attorney General of Texas, Greg Abbott, ("the State") and relators Tracy Miksell-Branch and Allison Zayas (collectively, "Plaintiffs").

4. Relator Tracy Miksell-Branch is a citizen of the United States and a resident of Iowa. From November 2000 until May 2010, Relator Miksell-Branch worked as an Executive

Pharmaceutical Sales Specialist (EPSS) in AstraZeneca's Central Nervous System ("CNS") division, where her primary duties and responsibilities entailed marketing Seroquel IR, and later, Seroquel XR. Through her employment at AstraZeneca as an EPSS, Relator Miksell-Branch gained a wealth of direct and independent knowledge of the fraudulent schemes perpetrated by the Defendants. Relator Miksell-Branch witnessed meetings and discussions related to AstraZeneca's schemes to maximize sales of Seroquel IR and Seroquel XR through means that included influencing, manipulating, and making misrepresentations to psychiatrists, pharmacists, and other health care professionals.

5. Relator Miksell-Branch resigned from AstraZeneca on May 10, 2010, as a result of threats, harassment, and other retaliation that she suffered after AstraZeneca disclosed to her regional and district managers, as well as to sales representatives in her district, that Relator Miksell-Branch had reported the Company's ongoing, illegal off-label promotion of Seroquel IR and Seroquel XR to AstraZeneca's compliance department. Relator Miksell-Branch also wished to disassociate herself from AstraZeneca's continuing illegal conduct.

6. Relator Allison Zayas is a citizen of the United States and a resident of New York. From May 2006 until November 2010, Relator Zayas was a Pharmaceutical Sales Specialist ("PSS") in AstraZeneca's CNS division, where her primary duties and responsibilities entailed marketing Seroquel IR, and later, Seroquel XR. Because of her position, Relator Zayas has unique knowledge of the sales and marketing efforts behind both Seroquel IR and Seroquel XR. Furthermore, because of her position, Relator Zayas has unique knowledge of how AstraZeneca unlawfully promoted Seroquel IR and Seroquel XR.

7. Relators originally provided information to the State of Texas, which is the basis for this suit. Relators filed their Original Petitions under seal, pursuant to the authority granted

by TEX. HUM. RES. CODE § 36.101, alleging Defendants' false statements, misrepresentations, and concealment of material information violated the TMFPA, TEX. HUM. RES. CODE § 36.001 *et seq.* Relators' allegations were based on their direct, independent, and personal knowledge and also on information and belief. Relators are original sources of the information underlying this First Amended Petition and provided such information to the State of Texas in their Disclosure Statements. Relators' Disclosure Statements presented substantially all material evidence and information they had in their possession at the time of the filing of their Original Petitions pursuant to TEX. HUM. RES. CODE § 36.102. Prior to filing her Original Petition, Relator Miksell-Branch brought the wrongdoing described herein to the attention of AstraZeneca.

B. Defendants

8. Defendant ASTRAZENECA, L.P. ("AstraZeneca L.P.") is organized under the laws of Delaware and has its principal place of business in Delaware, at 1800 Concord Pike, Wilmington, DE 19850. AstraZeneca L.P. is a wholly-owned subsidiary of AstraZeneca PLC. AstraZeneca L.P. marketed and distributed the drugs Seroquel IR and Seroquel XR in Texas. AstraZeneca L.P. conducts business in Texas.

9. Defendant ASTRAZENECA PHARMACEUTICALS, L.P. ("AstraZeneca Pharmaceuticals") is organized under the laws of Delaware and has its principal place of business in Delaware, at 1800 Concord Pike, Wilmington, DE 19850. AstraZeneca Pharmaceuticals is a wholly-owned subsidiary of AstraZeneca PLC. AstraZeneca Pharmaceuticals marketed and distributed the drugs Seroquel IR and Seroquel XR in Texas. AstraZeneca Pharmaceuticals conducts business in Texas.

10. Defendant ASTRAZENECA BIOPHARMACEUTICALS, INC. ("AstraZeneca Biopharmaceuticals") is incorporated in Delaware and has its principal place of business in

Delaware, at 1800 Concord Pike, Wilmington, DE 19850. AstraZeneca Biopharmaceuticals is a wholly-owned subsidiary of AstraZeneca PLC. AstraZeneca Biopharmaceuticals conducts business in Texas.

11. Defendant ASTRAZENECA PLC ("AstraZeneca PLC") is incorporated in the United Kingdom and has its principal place of business in London, at 2 Kingdom Street, London, W2 6BD. AstraZeneca PLC is the parent company of AstraZeneca L.P., AstraZeneca Pharmaceuticals, and AstraZeneca Biopharmaceuticals.[1] AstraZeneca PLC conducts business in Texas.

IV. JURISDICTION AND VENUE

12. This Court has jurisdiction of this action pursuant to TEX. HUM. RES. CODE § 36.101. Venue is proper in Travis County and this judicial district pursuant to TEX. HUM. RES. CODE § 36.052 (d). Moreover, the unlawful acts and omissions described herein occurred, in substantial part, in Travis County. Consequently, venue is proper in Travis County pursuant to TEX. CIV. PRAC. & REM. CODE § 15.002 (a) (1). Jurisdiction is further proper because the amounts sought from each Defendant exceed the minimum jurisdictional limits of this Court.

V. BACKGROUND

A. Atypical Antipsychotics and Associated Safety Risks

13. Second-generation antipsychotics, more commonly referred to as atypical antipsychotics ("atypicals"), are powerful drugs that were developed in the early 1990s as alternatives to first-generation or "conventional" antipsychotics for the treatment of serious and debilitating mental disorders, such as schizophrenia and bipolar disorder. In part as a result of their manufacturers' extraordinary – and often illegal – marketing efforts to portray the atypicals

[1] AstraZeneca PLC, AstraZeneca L.P., AstraZeneca Pharmaceuticals, and AstraZeneca Biopharmaceuticals are collectively referred to herein as "Defendants" or "AstraZeneca."

as safer, more effective, and appropriate for broader use than the similarly effective conventional antipsychotics, atypicals now account for about 90% of all antipsychotic prescriptions, despite many of those brand-name drugs being vastly more expensive than conventional antipsychotics.[2]

14. The perception that second generation antipsychotics are safe – more so than they actually are – has contributed to the increase in the prescribing of atypicals for a litany of off-label conditions, including: agitation; aggression; anxiety and generalized anxiety disorder ("GAD"); behavioral disorders, including ones related to dementia; obsessive compulsive disorder; major depressive disorder ("MDD") as monotherapy; post-traumatic stress disorder ("PTSD"); and personality disorders. The use of atypicals in these off-label conditions is unproven to be superior to placebo, and in some cases, is actually counter-productive to patient recovery.

15. Further, off-label atypical use in the child and adolescent population is also large and continues to grow. From 2004 to 2008, pediatric prescriptions of atypical antipsychotics dispensed by retail pharmacies increased from 3.94 to 4.8 million and accounted for 9% of all Seroquel IR prescriptions.[3] Children in the foster care system[4] have been particularly impacted by the trending increase in atypical usage. For example, in 2009, over 21% of foster children in Texas received at least one atypical (and oftentimes, multiple atypicals) for sixty days or more, a rate that was ten times higher than the national rate for non-foster children with Medicaid, and twenty times higher than the national rate for non-foster children with private insurance.

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[2] Patent exclusivity is the main driver of price for drugs in this class. Risperdal lost exclusivity in 2008; Zyprexa in 2011; Geodon, Seroquel IR, and Invega in 2012. Abilify and Seroquel XR continue to enjoy patent protection.

[3] At no point during this 2004-2008 time period did Seroquel IR have an indication for use in the child and adolescent population, thus making such use off-label.

[4] In Texas, the majority of foster children automatically qualify for Medicaid coverage.

16. The perception that atypical antipsychotics are "safer" than conventional antipsychotics, however, does not mean that atypicals are actually safe for the broad array of uses for which they have been marketed. On the contrary, use of atypicals, including Seroquel IR and Seroquel XR, is accompanied by the risk of numerous adverse events, among the most serious of which are: metabolic abnormalities that may lead to diabetes and weight gain; cardiac disorders; debilitating movement disorders; and cognitive impairment. In addition, use of each drug is accompanied by significant risks of hypotension, elevated liver enzymes (an indicator of liver damage), abdominal pain, constipation, dizziness, somnolence, and a litany of other cardiac,[5] digestive, musculoskeletal, and nervous system adverse events, including sudden death. These serious side effects can be particularly dangerous in the vulnerable pediatric and elderly populations. A recent study published in the *American Academy of Child and Adolescent Psychiatry* underscores the potential health risks of antipsychotic therapy, finding that the rate of developing diabetes more than doubled for children and adolescents who received antipsychotic therapy.[6] As well, the product labels for both Seroquel IR and Seroquel XR contain a black box warning that elderly patients with dementia-related psychosis who take either drug are at an increased risk for death.

17. As recognized by an FDA Advisory Committee convened to consider expanding the approved uses of Seroquel XR, whether a patient's exposure to Seroquel XR's significant risks is justified depends both on the seriousness of the disease being treated as well as the

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[5] A study published in 2009 in the New England Journal of Medicine found that patients taking Seroquel and other atypicals experienced a risk of sudden cardiac death that was more than double that of the ordinary population. Ray, et al., *Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death*, 360 New Eng. J. Med. 225 (2009).

[6] Nielsen, et al., *Risk of Diabetes in Children and Adolescents Exposed to Antipsychotics: A Nationwide 12-Year Case-Control Study*, 53.9 J. Am. Acad. Child Adolesc. Psychiatry 971 (2014).

availability of alternative, safer therapies. For patients with the most serious psychiatric diseases, such as schizophrenia and bipolar disorder, the risks of experiencing these adverse events may be justified. However, for other more common and less severe conditions, the efficacy benefit may be too small or uncertain to justify the risks. Indeed, Seroquel XR's side effect profile was critical to the FDA's determination to *not* approve Seroquel XR for treatment of GAD, and to *not* approve Seroquel XR as monotherapy to treat MDD; the FDA concluded that the demonstrated efficacy benefit was insufficient to balance Seroquel XR's known risks, particularly given the availability of other, safer treatments for these conditions.

B. Seroquel IR's FDA-Approved Indications

18. Seroquel IR is an atypical antipsychotic originally approved by the FDA in September 1997 for the acute treatment of schizophrenia in adult patients.

19. In January 2004, the FDA approved Seroquel IR for "short-term treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy[7] or adjunct therapy[8] to lithium or divalproex" in adult patients.

20. On October 20, 2006, the FDA approved Seroquel IR for the treatment of depressive episodes associated with bipolar disorder in adult patients.

21. On December 2, 2009, the FDA approved Seroquel IR as treatment for schizophrenia in 13- to 17-year-old adolescents, and for the acute treatment of manic episodes associated with bipolar I disorder in 10- to 17-year-old children and adolescents. These very limited approvals were the only indications that Seroquel IR received for the treatment of

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[7] Monotherapy is the use of a single drug to treat a particular disorder or disease.

[8] Adjunct therapy is the use of another treatment, in conjunction with the primary treatment, to assist the primary treatment.

children and adolescents. The FDA has never approved Seroquel IR for use in children under the age of 10.

22. At no point in time has FDA approved – or has AstraZeneca sought approval for – Seroquel IR to treat Major Depressive Disorder, either as a monotherapy or as an adjunctive therapy to an antidepressant.

C. Seroquel XR's FDA-Approved Indications

23. On May 17, 2007, the FDA approved Seroquel XR for the acute treatment of schizophrenia in adult patients. Defendants made Seroquel XR available for sale in the United States shortly thereafter in July 2007. On November 15, 2007, the FDA extended Seroquel XR's approval for maintenance treatment of schizophrenia in adult patients.

24. On October 8, 2008, the FDA approved Seroquel XR in adult patients as monotherapy for the acute treatment of the depressive episodes associated with bipolar I and bipolar II disorders; as monotherapy for acute treatment of manic and mixed episodes associated with bipolar I disorder; and as maintenance treatment for bipolar I disorder as adjunctive therapy to lithium or Depakote (divalproex sodium).

25. In February 2008, Defendants submitted a supplemental New Drug Application ("sNDA") to the FDA seeking approval of Seroquel XR to treat MDD as a monotherapy, adjunct therapy, and maintenance therapy. The FDA Advisory Committee determined that Seroquel XR was insufficiently safe for most of these uses and, on December 2, 2009, the FDA refused to approve Seroquel XR for broad use in treating MDD. The FDA limited its approval of Seroquel XR in MDD to adjunctive use to an antidepressant in patients who had an inadequate response to an antidepressant alone.

26. In May 2008, Defendants submitted an sNDA seeking approval of Seroquel XR to treat generalized anxiety disorder ("GAD"). The same FDA Advisory Committee that considered the MDD application also considered the GAD application and concluded that Seroquel XR was not safe for the treatment of GAD. The FDA followed the Advisory Committee's recommendation and refused to approve Seroquel XR for the treatment of GAD.

27. On April 30, 2013, the FDA approved Seroquel XR for two very limited groups within the child and adolescent population: the treatment of schizophrenia in 13- to 17-year-old adolescents; and the acute treatment of manic episodes associated with bipolar I disorder in 10- to 17-year-old children and adolescents. As with Seroquel IR, Seroquel XR has never been FDA-approved for use in children younger than 10.

D. The FDA Regulatory System

1. The Role of the FDA in Regulating Prescription Drug Promotion

28. In the United States, the sale and promotion of prescription drugs is regulated by the U.S. Food and Drug Administration ("FDA"), pursuant to the authority granted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. Under the FDCA, new drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the FDA "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof."[9,10] As well, the drug's sponsor must show by substantial evidence that the drug is safe for the conditions of use "prescribed, recommended, or suggested in the proposed labeling."[11] Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

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9 21 U.S.C. § 355 (d) (5).

10 "Substantial evidence," as used in this section, is defined at 21 U.S.C. § 355 (d) (7).

11 21 U.S.C. § 355 (d) (1).

29. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any clinical investigations itself. Applications for FDA approval of pharmaceutical products (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use."[12]

30. The FDCA requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness.[13] The FDA approves a drug if there are adequate and well-controlled clinical trials that demonstrate a drug's safety and effectiveness for its intended conditions of use.[14] Importantly, the FDA's determination of a drug's "safety" consists of a risk-benefit analysis that includes consideration of the severity of conditions for which the drug's approval is sought, as well as the other available treatments for such conditions.[15]

31. Once the FDA has approved a drug's NDA for a specific condition – an "indication for use" in FDA terminology – the drug's sponsor is legally only entitled to promote the drug for that particular indication.[16] In order to expand an approved drug's indications for use under the FDCA, the sponsor must submit – and FDA must approve – a supplemental New Drug Application ("sNDA") for each new intended use. In evaluating an sNDA, the FDA applies the same statutory standards for safety and effectiveness as with the original NDA,

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12 21 U.S.C. § 355 (b) (1) (A).
13 *See* 21 U.S.C. § 355 (d) (7).
14 *See* 21 U.S.C. § 355 (d) (5).
15 *See* 21 U.S.C. § 355 (d) (7).
16 Promotion of a drug for a non-indicated use is commonly referred to as "off-label promotion," and can serve as evidence that the drug's manufacturer created a new intended use for the drug. *See* Section V.D.2, *infra*.

including carefully balancing the drug's risks and benefits for the new potential indication for use.[17]

2. **FDA Regulations Prohibit the Misbranding of Prescription Drugs**

32. Under the FDCA, it is illegal to introduce into interstate commerce any drug that is misbranded.[18] A drug is misbranded if the labeling is false or misleading in any particular, the labeling does not contain adequate directions for use, or the manufacturer utilizes false or misleading advertisements relating to the drug.[19]

33. "Labeling" is a core concept of pharmaceutical regulation within the FDCA, and is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[20] Courts have interpreted labeling broadly to encompass printed material even when not physically attached or connected to the related pharmaceutical product.[21]

34. Pursuant to the authority granted by the FDCA, the FDA promulgated a series of regulations further expanding on the drug-related statutory requirements of the FDCA.[22] Under these regulations, 21 C.F.R. 201.5 defines "adequate directions for use" to mean "directions under which the layman can use a drug safely and for the purposes for which it is intended. (Section 201.128 defines "intended use.")." For prescription drug products that require the supervision of a medical professional to safely administer, 21 C.F.R. 201.100 clarifies that product labeling must contain "adequate information for such use ... under which practitioners

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17 *See* 21 U.S.C. § 355 (d) (7).
18 21 U.S.C. § 331 (a).
19 21 U.S.C. § 352 (a), (f), (n).
20 21 U.S.C. § 321 (m).
21 *See Kordel v. United States*, 335 U.S. 345 (1948).
22 *See* 21 C.F.R. 200-369.

licensed by law to administer the drug can use the drug safely *and for the purposes for which it is intended, including all conditions for which it is advertised or represented.*" (Emphasis added).

35. "Intended use" is defined by 21 C.F.R. 201.128 as referring "to the objective intent of the persons legally responsible for the labeling of drugs." Intended use "is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article." Furthermore, "this objective intent may ... be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." Intended use can also be shown circumstantially.

36. The FDA requires pre-approval of changes to prescription drug labels.[23] Thus, a manufacturer that creates a new "intended use" for its prescription drug product cannot unilaterally amend the label to include this new intended use;[24] rather, the drug will necessarily be misbranded at that point in time, in violation of the FDCA.

37. In sum, the misbranding regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body – the FDA. Moreover, the prohibition on false or misleading labeling claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on deceptive marketing tactics.

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[23] *See* 21 C.F.R. 314.50, 314.70. This provision does not apply to a drug company unilaterally adding newly-discovered drug safety information to the label. *Wyeth v. Levine*, 555 U.S. 555, 567 (2009).

[24] As discussed in Section V.D.1, *supra*, FDA requires "substantial evidence" of efficacy and safety, in the form of well-controlled clinical trials, for a new intended use to be approved for a drug.

3. **The Limited Role of the FDA in Regulating Prescription Drug Promotion**

38. The FDA's Office of Prescription Drug Promotion[25] ("OPDP") is charged with overseeing the marketing and promotion of approved drugs to ensure that drug promotion: (a) is not false or misleading; (b) provides a fair balance between the benefits and risks of the drug; and (c) does not misbrand the drug. *See* Statement by Janet Woodcock, M.D., Director Center for Drug Evaluation and Research, FDA, Before the Senate Special Committee on Aging (July 22, 2003).

39. OPDP's ability to regulate misbranding is limited. In 2003, its entire staff consisted of 40 members, with 25 reviewers responsible for reviewing all drug advertisements and promotional materials.

40. Moreover, materials promoting pharmaceutical products do not have to be pre-approved. FDA review of promotional materials occurs, if it does at all, after the materials have already appeared in public. *See* Woodcock Statement, *supra*. Upon finding a violation, OPDP generally requests the company to stop using the violative promotional materials. *Id.* OPDP occasionally requires sponsors to publicly correct product misimpressions created by materials that are false, misleading, and/or lacking in fair balance. *Id.*

E. Defendants Specifically Targeted the Texas Medicaid Program

41. Schizophrenic adults represent less than one percent (1%) of the United States population, while estimates of adults with bipolar disorder range from two percent (2%) to three percent (3%). Adults with severe mental illness such as schizophrenia and bipolar disorder are more likely to be uninsured, unemployed, impoverished, and therefore, unable to afford Seroquel IR or Seroquel XR (collectively, the "Seroquel Franchise"). Consequently, Defendants

[25] Formerly known as the Division of Drug Marketing, Advertising, and Communications (DDMAC).

anticipated that a significant portion of Seroquel Franchise revenue would be derived from public sector payors, such as Texas Medicaid.[26] Understanding the need to obtain significant government buy-in to achieve their financial goals for the Seroquel Franchise, Defendants set their sights on Texas Medicaid, declaring it "low hanging fruit" and "an ABSOLUTE MUST WIN" that would fuel brand growth.

F. Texas Medicaid

1. Overview

42. The state and federal governments fund health care for the poor and mentally ill through public health assistance programs. Government assistance programs incur the vast majority of the prescription drug costs associated with the treatment of mental illness in the United States. The Medical Assistance Program in Texas, commonly referred to as Texas Medicaid, was created to provide medical assistance for low-income individuals and families in Texas. Since January 2007, over 70% of Texas Medicaid enrollees have been 18 years of age or younger.[27]

43. The Texas Medicaid program, which includes Texas Medicaid decision makers as well as Texas Medicaid providers, is a system that provides medical products and services to qualified recipients. Texas Medicaid reimburses participating providers for the approved pharmaceuticals they provide to Medicaid recipients. The program is funded jointly by the State of Texas and the federal government. The Texas Health and Human Services Commission ("HHSC") administers the Texas Medicaid program and has authority to promulgate rules and other methods of administration governing the program.

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[26] Documents specific to Defendants' conduct in Texas describe Texas Medicaid as being their "number one payer" in the state.

[27] *See* http://www.hhsc.state.tx.us/research/MedicaidEnrollment/ME-Monthly.asp.

2. Texas Medicaid Tools for Managing Appropriate and Cost-Effective Pharmaceutical Therapy

44. The Vendor Drug Program ("VDP") within HHSC was established to oversee the outpatient prescription drug portion of the Texas Medicaid program, and was in operation at all times relevant to this case.

45. Providers can obtain reimbursement through VDP for pharmaceutical products approved for use and reimbursement under this program, and which are listed on the VDP formulary.[28] Texas Medicaid, like all state Medicaid programs, is only authorized by federal law to reimburse for "covered outpatient drugs" and is not authorized to reimburse for drugs that are used for an indication which is not "medically accepted." An indication or use is not "medically accepted" unless it is approved by the FDA or supported by at least one of three compendia enumerated under the Federal Medicaid Act. *See* 42 U.S.C. § 1396r-8(k)(3), (6); 42 U.S.C. § 1396r-8(g)(1)(B)(i).

46. To have its particular pharmaceutical products listed on the VDP formulary, a drug company or manufacturer must file an application with VDP.[29] Included in the application is a detailed 16-point questionnaire that, pursuant to state law, must be completed and filed. Texas Medicaid requires information provided to it by pharmaceutical manufacturers as part of the VDP application process to be complete, truthful, and up-to-date.[30]

47. VDP applications require drug manufacturers to report, for each drug submitted, the recommended daily dosages, formulation of the drug, FDA approval letters, and copies of the package inserts and materials for physicians. The VDP application also requires manufacturers

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[28] 1 TEX. ADMIN. CODE § 354.1831 (a). The VDP formulary is also referred to as the Texas Drug Code Index or "TDCI."

[29] 1 TEX. ADMIN. CODE § 354.1921 (b).

[30] *Id. See also* 1 TEX. ADMIN. CODE § 354.1923 (b).

to certify that all the information provided with their application is correct and that their drug is not in violation of either state or federal law. The application further requires manufacturers, on a going-forward basis, to submit notification of any changes pertaining to their product's status within fifteen (15) days of such changes occurring.

48. In approving VDP applications, HHSC expressly provides that manufacturers are responsible for submitting notification of changes pertaining to the 16 points specified in the application no later than the date such revisions are scheduled to occur. Accordingly, manufacturers owe a continuing duty to Texas Medicaid to supplement information provided with their VDP application after its initial submission to the VDP. Moreover, a new VDP application must be submitted each time a drug first becomes available in a new formulation or in different dosages.

49. Pharmaceutical manufacturers' interactions with Texas Medicaid, and Texas Medicaid's review of drugs placed on its formulary, do not stop with submission of the initial VDP application. Texas Medicaid has an on-going obligation to manage its drug formulary through Drug Utilization Review ("DUR") in accordance with the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90"). Pursuant to that obligation, Texas Medicaid created the DUR program to promote optimal and cost-effective pharmaceutical therapy in the Texas Medicaid VDP.[31]

50. Specifically, the DUR program exists to ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical outcomes. The program is designed to educate pharmacists and physicians to identify and reduce the frequency of patterns

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[31] 1 TEX. ADMIN. CODE § 351.3 (3).

of fraud, abuse, overuse, or inappropriate or medically unnecessary care associated with specific drugs or groups of drugs.

51. The DUR Board has a number of tools available to it to achieve these goals, including prior authorization, educational letters expressing therapeutic concerns to Texas Medicaid providers, DUR alerts, and clinical edits. If necessary, the DUR Board initiates recommendations that certain drugs be made subject to prior authorization or to restrictions concerning the types of patients (*e.g.*, children, elderly persons, etc.) or the types of conditions for which Medicaid reimbursement is obtainable.

52. As part of this program, the DUR Board monitors and analyzes provider-level activity. Drug manufacturers, including Defendants, provide the DUR program with information concerning their drugs. The DUR program expects – and Texas law requires – all such provided information to be complete and accurate.

53. By way of example, due in part to the great expense and serious potential side-effects associated with atypical antipsychotics, the DUR Board has mailed out a number of retrospective intervention letters targeting unproven atypical use. One such retrospective intervention from June 2007 was proposed as a result of observed increases in atypical antipsychotic utilization,[32] including off-label uses. Concerns about this increased atypical use led the DUR Board to approve the proposed intervention, resulting in intervention materials being mailed to a target group of over 3,800 Texas physicians. Additionally, where the DUR Board has specific evidence of improper conduct, even more stringent initiatives can be taken. For instance, in April 2008, the DUR Board implemented a clinical edit targeting the widespread usage of low dose Seroquel IR as a sleep aid, stemming, in part, from AstraZeneca's illegal

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[32] At this time in 2007 there were six available atypicals: clozapine, Risperdal, Seroquel IR, Zyprexa, Abilify, and Geodon.

promotion of the 50mg tablet, which was below the lowest dose for any FDA-approved condition. However, the DUR Board's ability to take such restrictive action is limited by its knowledge of the unlawful conduct. Thus, the DUR Board cannot effectively address issues of improper utilization where the illicit promotional scheme is concealed by the drug company.

54. In February 2004, Texas Medicaid implemented another means through which Texas Medicaid could manage its expenditures for pharmaceuticals – the Texas Medicaid Preferred Drug List (the "PDL").[33] In making recommendations for the PDL, the Texas Medicaid Pharmaceutical and Therapeutics Committee (the "P&T Committee") considers the clinical efficacy, safety, and cost-effectiveness of each drug reviewed.[34] As part of this PDL process, the P&T Committee receives information from drug manufacturers, including Defendants, concerning their drugs. The P&T Committee expects – and Texas law requires – all such information to be complete and accurate. HHSC then decides which drugs are placed on the PDL based on P&T Committee recommendations, the cost of competing drugs to the state, clinical considerations, written information offered by manufacturers about their products, and the existence of a supplemental rebate agreement and/or other program benefits. Drugs that are reviewed but not selected for the PDL require prior authorization. Defendants sought and achieved the placement of both Seroquel IR and Seroquel XR on the PDL without prior authorization, including by making presentations to the P&T committee and submitting written information to the State and/or State contractors concerning Seroquel IR and Seroquel XR. As with the DUR Board, the P&T Committee cannot effectively make recommendations to manage the preferred drug list where material information has been misrepresented and/or concealed by a drug company.

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33 1 TEX. ADMIN. CODE § 354.1924.

34 1 TEX. ADMIN. CODE § 354.1928.

3. The Texas Medicaid Program

55. As discussed above, Texas Medicaid includes not just the Medicaid decision makers such as the VDP, DUR, and P&T committee members, but also Medicaid providers such as pharmacies and physicians, which enter into agreements with Texas Medicaid in order to be covered providers. Together, Texas Medicaid decision makers and providers constitute the Texas Medicaid program. The Texas Medicaid Fraud Prevention Act seeks to protect against fraud at all levels of the Texas Medicaid program. *See* TEX. HUM. RES. CODE § 36.001 *et seq.*

VI. APPLICABLE TEXAS STATUTORY AND COMMON LAW

56. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 55 of this Petition.

57. A person commits an unlawful act as defined under the Texas Medicaid Fraud Prevention Act by, among other things:

A. Knowingly making or causing to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE § 36.002 (1).

B. Knowingly concealing or failing to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE § 36.002 (2).

C. Knowingly making, causing to be made, inducing, or seeking to induce the making of a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program. TEX. HUM. RES. CODE § 36.002 (4) (B).

D. Knowingly paying, charging, soliciting, accepting, or receiving, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program. TEX. HUM. RES. CODE § 36.002 (5).

E. Knowingly engaging in conduct that constitutes a violation under TEX. HUM. RES. CODE § 32.039(b). TEX. HUM. RES. CODE § 36.002 (13).

Hereinafter, references to conduct as constituting "statutory fraud" mean that the conduct being described was done by Defendants at times when one or more of the statutory provisions set forth in this Paragraph 57 applied, and was done in ways and through means that satisfy all the required elements of at least one applicable statutory provision.

58. Under Texas common law a person commits fraud by:

A. Making representations of material facts that are false, with knowledge that such representations are false, or by making misrepresentations recklessly, as a positive assertion, and without knowledge of their truth, with the intent that the victim act upon such representations; or by

B. Failing to disclose material facts within that person's knowledge, which he had a duty to disclose, knowing that the victim is not aware of the concealed facts and does not have an equal opportunity to discover the truth, with the intent to induce the victim to take action by failing to disclose those facts.

Hereinafter, references to "common law fraud" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in Subparagraph A or B of this Paragraph 58.

59. Under Texas law it is illegal for persons to actively encourage, induce, or assist a fiduciary to breach his fiduciary duties. Persons commit this unlawful act by knowingly participating in a fiduciary's breach of his fiduciary duties owed to the victim, if such wrongdoers knew, or reasonably should have known, that their conduct would cause the fiduciary to breach the fiduciary duties owed to the victim. Hereinafter, references to "aiding or abetting breach of fiduciary duty" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in this Paragraph 59.

60. Under Texas law, a person commits the tort of negligent misrepresentation if, in the course of his business or transactions in which he had pecuniary interests, he supplies information that is false, for the guidance of others, and he fails to exercise reasonable care or competence in obtaining or communicating the information. Hereinafter, references to "negligent misrepresentation" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in this Paragraph 60.

61. Under Texas law, if a victim, unaware of a wrongdoer's unlawful acts, pays money that would otherwise not have been paid, such that the wrongdoer holds money that in equity and good conscience belongs to the victim, the retention of those funds by the wrongdoer would be inequitable and unjust. Hereinafter, references to "monies had and received" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in this Paragraph 61.

62. Under Texas law, a victim can recover under promissory estoppel if a wrongdoer made a promise to the victim, the victim reasonably and substantially relied on the promise to its detriment, the wrongdoer could have foreseen the victim's reliance on the promise, and injustice can be avoided only by enforcing the wrongdoer's promise. Hereinafter, references to "promissory estoppel" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in this Paragraph 62.

VII. DEFENDANTS' UNLAWFUL ACTS

63. In 2006 Defendants were made aware of a joint federal and state investigation (the "2006 Investigation") into the promotion of Seroquel IR, including allegations that Defendants unlawfully promoted Seroquel IR for use in depression and within the child and

adolescent population.[35] In an attempt to quietly resolve these allegations, Defendants began negotiating towards a settlement agreement.

64. Settlement negotiations continued into 2010, at which time Defendants agreed to pay $520 million for dismissal of the claims associated with the 2006 Investigation.[36] Additionally, Defendants entered into a Corporate Integrity Agreement ("CIA") with the U.S. Department of Health and Human Services' Office of the Inspector General ("OIG"), which imposed a number of compliance-related obligations upon the company, including internal company oversight and various reporting requirements. This settlement covered Defendants' promotional conduct relating to Seroquel IR from January 2001 through December 2006.

65. Far from being a good corporate citizen, Defendants did not alter their unlawful promotional tactics even after learning about the allegations in the 2006 Investigation. In fact, one of the few actions Defendants took in advance of the impending 2010 settlement was to eliminate free-text call notes, a major source of evidence for government regulators, which had the effect of further concealing their ongoing unlawful promotional scheme.

66. In 2007 and beyond, Defendants continued promoting Seroquel IR in a manner that caused the drug to be misbranded, while concurrently negotiating for a settlement. This unlawful scheme later transitioned to Seroquel XR in 2009, when Defendants became concerned regarding the limited remaining duration of the Seroquel IR patent.

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[35] Such off-label promotion may serve as evidence of a new intended use for the drug, resulting in the drug being unlawfully misbranded.

[36] *See* http://www.justice.gov/opa/pr/2010/April/10-civ-487.html.

A. Defendants Promoted the Seroquel Franchise for Use in the Child and Adolescent Population, Misbranding the Products in Violation of Federal and State Law

67. At no point during the time that Defendants promoted Seroquel IR[37] did Seroquel IR have an indication for use in the child and adolescent population. Similarly, at no point prior to April 2013 did Seroquel XR have an indication for use in the child and adolescent population. Yet, at all times prior to April 2013, Defendants required the CNS sales force to promote the Seroquel Franchise to doctors named on a company-provided list of physicians – the "call plan" – that included a significant number of child and adolescent psychiatrists.

68. Furthermore, at all relevant times Defendants incentivized off-label promotion through the "Field Sales Incentive Plan" ("FSIP") by rewarding sales representatives equally for off-label and on-label prescriptions. Sales representatives were evaluated based on, and provided with monetary incentives for, the total volume of Seroquel Franchise prescriptions generated in their territory, regardless of why or to whom the doctor wrote the prescription.

69. Defendants understood at least by 2006, when the first Seroquel investigation was partially unsealed, that it was unlawful to promote Seroquel for use in the child and adolescent population, absent having an appropriate pediatric indication. Yet, in response to learning of – and beginning settlement negotiations for – the 2006 Investigation, Defendants wholly failed to alter the systematic manner in which they targeted child and adolescent psychiatrists. Instead, Defendants merely concealed their overt pediatric promotional efforts while continuing to require the CNS sales force to make hundreds of calls to child and adolescent psychiatrists on a weekly basis.

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[37] Defendants switched all promotional efforts from Seroquel IR to Seroquel XR in February 2009 in anticipation of Seroquel IR's patent protection expiring. Seroquel IR later gained a limited pediatric indication in December 2009, ten months after all promotion for the drug had ceased.

70. Moreover, Defendants had full knowledge of what actions could have been taken to curb off-label pediatric promotion. Shortly after becoming aware of the 2006 Investigation, one e-mail between Defendants' Targeting and Performance ("T&P") team and national sales leadership noted that Defendants' legal team may ask T&P to remove non-indicated physicians (*i.e.*, child and adolescent psychiatrists) from being counted towards sales representative incentive compensation, in order to avoid encouraging misleading and off-label promotion. Despite being aware of this potential solution, no such wholesale off-label script exclusion was implemented by Defendants, and Seroquel IR's pediatric market share continued to grow.

71. Defendants additionally understood exactly what was at stake, in terms of potential sales dollars, if they were to end pediatric promotional efforts. In a 2008 e-mail, Defendants' CNS National Sales Director asked the T&P team to perform an analysis showing what the impact in sales would be if all child and adolescent psychiatrists were removed from CNS call plans. The T&P team responded that Defendants would stand to lose $113.8 million annually if this change occurred, noting that "the impact could be significant" and that this was "a substantial amount of business to have no promotional efforts." Following this exchange, no such change was made to eliminate pediatric promotion of the Seroquel Franchise.

72. Simply put, Defendants prioritized increasing sales figures over complying with federal and state regulations, leading the national sales leadership to reject solutions to one of the main issues that gave rise to the 2006 Investigation. Further, these two e-mail exchanges evidence Defendants' high-level intent to expand the Seroquel Franchise within the child and adolescent population at a time when neither drug had an appropriate indication, while Defendants continued to negotiate for a settlement in the 2006 Investigation.

73. In furtherance of this objective, Defendants' Seroquel Franchise Brand Team closely tracked Seroquel IR's market share in the pediatric population. Defendants' internal documents show that Seroquel IR's growth in this off-label population trended upward until around mid-2008, when Seroquel's main competitor, Abilify, obtained an FDA indication for use in the child and adolescent population.

74. As could be expected, the effect of Defendants' high-level intent to grow the Seroquel Franchise in the pediatric population cascaded down to the regional and district levels, creating a sales environment in which off-label promotion of the Seroquel Franchise for use in children was encouraged and rewarded.

75. Both nationally and in Texas, Defendants' CNS call plans consisted of around ten to fifteen percent child and adolescent psychiatrists. However, in Texas, these ten to fifteen percent typically accounted for a disproportionately-high amount of total Seroquel Franchise prescription volume within a sales representative's territory. For example, within the San Antonio district, CNS sales representatives noted that child and adolescent psychiatrists constituted approximately 70% of their total territory volume. Likewise, in the Dallas district, child and adolescent psychiatrists were described as "dominat[ing] and driv[ing] our book of business," with six of ten top accounts being child and adolescent psychiatrists in one territory. For these sales representatives, it would have been impossible to achieve the sales quotas established by Defendants' sales leadership without promoting to their respective territory's high-volume child and adolescent psychiatrists.

76. Defendants additionally utilized the following promotional tactics to improperly expand usage of the Seroquel Franchise in the pediatric population:

- Hiring influential child and adolescent psychiatrists as Key Opinion Leaders ("KOLs") to discuss using the Seroquel Franchise with other child and adolescent providers during lunch and dinner speaker programs;
- Creating "Abilify Offender" lists, which identified and targeted high-Abilify-prescribing psychiatrists, many of whom were child and adolescent providers, at a time when Abilify had a child and adolescent indication and the Seroquel Franchise did not; and
- Targeting Texas Medicaid providers, many of whom (as a result of the demographics of Texas Medicaid enrollees) served large child and adolescent populations.

77. Defendants misleadingly promoted the Seroquel Franchise to child and adolescent psychiatrists to increase the utilization of the Seroquel products for children – which was in fact achieved. By promoting the Seroquel Franchise in this manner, Defendants knew or reasonably should have known that the drugs would be widely used off-label for children, thus creating a new intended use for Seroquel IR and Seroquel XR. As a result of this promotional scheme, Defendants caused the Seroquel Franchise to be misbranded in violation of federal and state law.

B. Defendants Promoted Seroquel IR for Use in Depression, Misbranding the Product in Violation of Federal and State Law

78. At least as early as 2005, Defendants were aware that Seroquel IR was gaining market share in off-label conditions, including depression, while market share for schizophrenia was declining. In order to continue growing Seroquel IR in the off-label depression market, Defendants developed a high-level strategy within their 2006 Product Strategic Plan to promote Seroquel IR by claiming it was effective for use in "a broad range of depressive symptoms such as anxiety." This type of broad symptom-based promotion fails to distinguish between the

various mood disorders, including MDD, and misleadingly suggests that Seroquel IR is effective and/or indicated for the treatment of MDD, as MDD and bipolar depression share the same core set of depressive symptoms.

79. After obtaining Seroquel IR's bipolar depression indication in October 2006, Defendants held a company-wide Business Emphasis Meeting ("BEM") to disseminate the new Seroquel IR promotional strategy to the entire CNS sales force and to train the sales force to use these messages through a series of hands-on workshops. Maintaining the high-level plan established the prior year, Defendants included among the strategic messages that "Seroquel helps reduce their depression, irritability, racing thoughts and anxiety symptoms." Defendants further focused on this broad symptom-based sales approach by generally referring to Seroquel IR's efficacy in depressive symptoms, and by specifically referencing Seroquel IR's efficacy in each individual MADRS symptom.[38]

80. Following this BEM and into 2007, Defendants' CNS sales teams throughout Texas implemented Defendants' plan to misleadingly position Seroquel IR broadly for use in depressive symptoms. E-mails show CNS District Sales Managers ("DSMs") sending reminder messages to their sales force emphasizing the broad symptom-based sales approach as dictated by Defendants' national sales strategy. Understanding the clear direction from sales leadership, sales representatives systematically delivered the broad symptom-based messages to Texas healthcare providers, including providers participating in the Texas Medicaid program and providers appointed as Texas Medicaid decision makers. Numerous call notes and Field

[38] "MADRS" refers to the Montgomery–Åsberg Depression Rating Scale ("MADRS"), which measures the severity of depressive episodes in patients with mood disorders. Measured components within the MADRS include apparent and reported sadness, inner tension, and reduced sleep, among others.

Coaching Forms (FCFs) reflect the implementation of this symptom-based sales approach at the local level within Texas.

81. Sales representatives were periodically required by their DSMs to formulate a "territory plan," which involved taking the company-driven messaging and adapting it for local use. One example of a territory plan is seen in a Houston district in 2008, where the sales representatives developed a plan focusing "on educating the physicians on the rise in depressive symptoms during this specific time of year. We will use the [MADRS] and point out specific symptoms that [patients] may present with because of the holidays."

82. By all accounts, Defendants' effort to broadly and misleadingly promote their potent antipsychotic medication for use in depression was a success. Defendants understood that depression was an off-label condition for Seroquel IR, yet Defendants closely tracked Seroquel IR's market share and performance within the MDD population. When growth in the MDD population appeared to slow, such as in mid-2008 when competitor antipsychotic Abilify obtained an adjunctive-MDD indication, Defendants took notice. Defendants' documents noted that Abilify was ramping up on-label MDD promotion "into the depression space where Seroquel should be the clear leader." Nonetheless, by 2008, Seroquel IR's off-label market share in MDD was greater than its on-label market share in bipolar depression, which (by virtue of the physicians targeted in Defendants' call plans) would have included a significant number of prescriptions for depressed and anxious pediatric patients.

83. Internally, Defendants recognized the success of this promotional campaign and expanded their goals to "[e]stablish Seroquel as a future 1st choice atypical for patients with MDD or GAD." Similarly, in a separate e-mail, Sales Team leadership noted that "[t]he launch success for future indications for SEROQUEL, like MDD and GAD, depends on building a solid

foundation [today] in depressive symptoms."[39] Establishing Seroquel as a "future 1st choice" or laying the foundation for an off-label indication necessarily requires present off-label promotion. To further their objectives, Defendants sought to utilize KOLs, publications, advisory boards, and other promotional tactics.

84. Defendants' planning and promotion of Seroquel IR for use in depressive symptoms was carefully calculated to reach beyond patients diagnosed with bipolar disorder and into the off-label unipolar depressed (MDD) population. By planning to promote, and then promoting, Seroquel IR in this false and/or misleading manner, Defendants created a new intended use and/or disseminated false and/or misleading advertisements for Seroquel IR, causing the drug to be misbranded in violation of federal and state law.

C. Defendants Promoted Seroquel XR for Broad Use in Depression and as an "Antidepressant," Misbranding the Product in Violation of Federal and State Law

85. As part of Defendants' plan to expand the use of Seroquel beyond the most severe and debilitating psychiatric disorders, and into MDD and GAD, Defendants performed preliminary market research in the MDD and GAD populations to determine how best to approach these conditions. Defendants discovered, however, that the physicians most frequently involved in diagnosing and treating these more-common conditions – Primary Care Physicians ("PCPs") – were reluctant to prescribe atypical antipsychotics such as Seroquel for broad use in depression, for fear of the litany of side effects associated with this class of potent medications. Defendants' market research also revealed that PCPs instead preferred mood stabilizers and antidepressants, which had different side effect profiles. As described by Defendants' "XR Immersion Day" presentation in 2008, atypicals (including Seroquel) were perceived as "big

[39] "Today" appears in brackets in Defendants' document, as a suggested addition to the document.

guns with big baggage" by PCPs; likewise, the term "atypical antipsychotic" was itself viewed as being "conceptually confining" by the "Seroquel Science Strategy Team Update" in 2008.

86. Utilizing this information, Defendants saw an opportunity to differentiate Seroquel XR, both from atypicals generally and from Seroquel IR specifically: rather than launching it as another atypical antipsychotic, Defendants planned to launch Seroquel XR as an *antidepressant*. By misleadingly promoting Seroquel XR as an antidepressant, Defendants would effectively conceal Seroquel XR's class-wide side effects typically associated with atypicals, and simultaneously reach the broader depression market, while creating the illusion that it was an entirely new medication for different purposes, and not just an extended-release version of Seroquel IR. Indeed, Defendants' "CNS Long Term Training Plan" from 2008 describes the deception of "[c]hanging the physician's mindset to view Seroquel as an efficacious antidepressant rather than an atypical antipsychotic" as being one of the "Challenges" facing the company in 2009.

87. To further this scheme, Defendants drastically altered the call plans of the CNS sales force in mid-2008 by adding a significant number of general practice PCPs, who Defendants knew would be seeing a large number of MDD and GAD patients. Up to that point, the CNS sales force had primarily called on psychiatric specialists.

88. In late December 2008, FDA informed Defendants that Seroquel XR would not be receiving an MDD indication as Defendants had anticipated, due to FDA having insufficient information regarding Seroquel XR's long-term risks in this more-common, non-psychotic, population. Additionally, FDA noted, there already existed a number of available effective MDD treatments, including SSRIs[40] and SNRIs[41] (among others), commonly referred to as

[40] Selective serotonin reuptake inhibitors.

"antidepressants," which did not have the long-term safety risks that Seroquel XR has.

89. Undeterred by FDA's denial of the MDD indication, Defendants nominally refocused the previously planned Seroquel XR MDD launch to the existing bipolar depression indication, in what the Brand Team referred to as the "new direction." In actuality, Defendants' "new direction" consisted of maintaining the same sales goals, same method of accomplishing the sales goals (via misleadingly rebranding Seroquel XR as an antidepressant), and same MDD disease-state training as had been established for the MDD indication launch. For instance, in anticipation of the potential MDD indication, which would have greatly expanded the on-label patient base for Seroquel XR, Defendants planned to increase the sales quotas for sales representatives. This planned increase was implemented even after the MDD indication was denied by FDA, forcing sales representatives to find new ways to achieve sales of Seroquel XR. Defendants also maintained the strategy of targeting patients that were diagnosed with MDD and unsatisfied with their current treatment – an off-label population – and misleadingly promoting Seroquel XR for use in individual depressive symptoms. This resulted in numerous false and/or misleading promotional messages that Defendants intended to use to obtain market share in the off-label MDD population, including, but not limited to:

- Positioning Seroquel XR as an effective monotherapy antidepressant;
- Focusing on a patient type that is diagnosed with MDD, being treated with an SSRI or SNRI, or another atypical, but still experiencing depressive symptoms;
- Stating that Seroquel XR is effective in treating particular depressive symptoms such as sadness, loss of interest, and feelings of worthlessness; and

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41 Serotonin–norepinephrine reuptake inhibitor.

- Selling against Abilify, which had an adjunctive-MDD indication at the time of Seroquel XR's launch.

90. Consistent with Defendants' national brand strategy, Defendants' sales representatives in both the CNS and MCL[42] sales force teams were trained to deliver, and consistently delivered, these false and/or misleading promotional messages to Texas healthcare providers, including providers participating in the Texas Medicaid program and providers appointed as Texas Medicaid decision makers. Ultimately, Defendants' promotion of Seroquel XR as an antidepressant was successful in expanding the market of Seroquel XR for broad use in depression, which as a result of the physicians targeted in Defendants' call plans, would have included a significant number of depressed pediatric patients.

91. Not all sales representatives were aligned with Defendants' new Seroquel XR launch messaging. In the spring of 2009, a Dallas-based sales representative made an audio recording of a district teleconference wherein the DSM sought to share best practices from the field, and to reinforce Defendants' brand messaging. Sales representatives on this recorded teleconference discussed recent interactions with the CNS Regional Sales Director ("RSD") covering the South Central Region, which included Texas and several other states. Among the messages relayed by the RSD to the sales representatives were misleading messages intended to increase the use of Seroquel XR for depression and as an antidepressant, which was in-line with the Seroquel XR national brand strategy.

92. This Dallas-based sales representative reported her DSM and RSD to Defendants' compliance department for off-label promotion. As part of this report, the sales representative

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[42] MCL (Medical Care Left) was another branch of Defendants' sales force, which promoted Seroquel IR and Seroquel XR, among other AstraZeneca drugs, primarily to family doctors (PCPs) and internal medicine practitioners.

submitted her audio recordings from the district teleconference. Defendants, despite having concrete evidence of off-label promotion occurring in the South Central Region, took no action for several months.

93. In October 2009, Defendants circulated an internal memo to its entire Seroquel sales force stating that the sales force must ensure "proper communication" of Seroquel XR's indications. Provided in this memo were examples of improper Seroquel XR messages, including messages relating to promoting Seroquel XR as an antidepressant, promoting Seroquel XR for use in patients diagnosed with MDD, and promoting Seroquel XR for the individual symptoms of depression. Defendants additionally terminated the RSD implicated in the audio recordings and demoted several DSMs around Texas. Yet, Defendants' corrective efforts were merely superficial, as Defendants did not address that the National Brand Team was responsible for the improper messaging. Numerous e-mails and documents show that the Brand Team was not only aware of the improper messaging being disseminated at the regional level, but was the very source of said improper messaging. In spite of this internal memo, Defendants continued to refer to Seroquel XR as an "antidepressant" into 2010 and beyond.

94. Defendants' planning and promotion of Seroquel XR for use as an "antidepressant" and in the depressed population demonstrates Defendants' intent to reach beyond bipolar depressed patients and into the off-label MDD population. By planning to promote, and then promoting, Seroquel XR in this false and/or misleading manner, Defendants created a new intended use and/or disseminated false and/or misleading advertisements for Seroquel XR, causing the drug to be misbranded in violation of federal and state law.

D. Defendants Provided Illegal Kickbacks to, and Unduly Influenced, Texas State Mental Health Officials and Decision Makers, in Violation of State Law

95. In an effort to increase utilization of the Seroquel Franchise within Texas, Defendants sought to influence decision-making within the Texas medical community generally, and the Texas state hospital system[43] specifically, by providing illegal payments to at least two state hospital employees.[44]

96. Defendants' e-mails and documents show Defendants knew that state hospital inpatients commonly maintain their medications upon discharge, at which time reimbursement for many of those medications would be through Texas Medicaid. Accordingly, Defendants targeted Texas state hospitals, in part, for the purpose of increasing Texas Medicaid utilization.

97. In furtherance of this objective, from at least 2008 to present, Defendants paid over $465,000 to two state mental health officials with the power to influence formulary decisions within the state hospital system.[45] Defendants ostensibly made these payments for promotional speaking engagements; however, Defendants' internal e-mails and documents reveal that Defendants' motivation for paying these two state mental health officials was actually: 1) to use them to influence the DSHS Executive Formulary Committee ("EFC"); and 2) to induce them to recommend use of the Seroquel Franchise to other Texas healthcare providers, particularly, to other state hospital, MHMR, and Medicaid providers, based on their positions as state officials.

98. For instance, in an October 2008 e-mail, one of Defendants' Institutional Sales Specialists (ISS) discusses Defendants' efforts to use state mental health officials to serve as

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[43] State hospitals in Texas are administered by the Department of State Health Services ("DSHS") and are funded, in part, by Medicaid, on a capitated basis. Texas state hospitals primarily serve patients on an inpatient basis.

[44] State hospital employees are public servants and employees of Texas.

[45] State hospitals use a drug formulary as established by the DSHS Executive Formulary Committee – separate from VDP.

Defendants' proxies in recommending that Seroquel XR be added to the DSHS formulary. During this discussion, the ISS explicitly describes Defendants' motive behind paying the state mental health officials: "While I have attached the Executive Formulary Committee Members names and attendance over the last year, let us not forget the non-committee members who can truly help us. [The AstraZeneca-paid state mental health officials] **are very influential** in the DSHS system." (Emphasis added).

99. This conduct continued into 2009, when Defendants were able to obtain a formal recommendation from one of the AstraZeneca-paid state mental health officials to request addition of Seroquel XR to the DSHS formulary. In preparation for the EFC's upcoming vote relating to the addition of Seroquel XR, in May 2009, one of Defendants' RSDs scheduled a Texas state hospital formulary strategy conference, wherein the two paid state mental health officials were referred to as being "key influencers" and "champions" that would be used to leverage their relationships with EFC voting members. In June 2009, the RSD followed up with a "Texas State Formulary Strategy Update," wherein an ISS was paired with a state mental health official for the purpose of targeting and influencing EFC voting members, on Defendants' behalf. Such conduct additionally exemplifies how Defendants' influence over the paid state mental health officials resulted in those state-employed doctors placing Defendants' interests ahead of state interests.

100. As late as December 2010, Defendants' internal documents refer to the two AstraZeneca-paid state mental health officials as being Defendants' "strongest advocates." As well, Defendants' own employees took credit for achieving utilization of XR at one of the state hospitals, despite XR not being on the state formulary, by building advocacy with the hospital's clinical director – one of the AstraZeneca-paid state mental health officials.

101. Beyond attempting to affect formulary decisions in the state hospital system, Defendants also induced the state mental health officials to recommend that other healthcare providers use the Seroquel Franchise, including providers participating in the Medicaid program. Defendants' documents in 2008 and 2009 show that Defendants used the AstraZeneca-paid state mental health officials to target healthcare providers that were perceived as being infrequent prescribers of the Seroquel Franchise. Indeed, Defendants explicitly planned in 2009 to "grow XR utilization" by "leverage[ing]" the AstraZeneca-paid state mental health officials within state hospitals and MHMR systems. Following such a visit with the AstraZeneca-paid state mental health officials, Defendants' sales representatives would often note an associated increase in Seroquel Franchise utilization. The substance of the presentations provided by these AstraZeneca-paid state mental health officials is revealed in Defendants' "Seroquel XR: 2010 Speaker Training Update" as being "promotional content" developed by Defendants and provided in slideshow format to the state mental health officials.

102. By paying large sums of money to state mental health officials for the purpose of utilizing their influence over the EFC, local formularies, and Texas healthcare providers, Defendants violated the state anti-kickback statute and thereby violated the TMFPA. Additionally, the state mental health officials referenced in this Section were persons who owed a fiduciary duty to the State of Texas, and Defendants' conduct in this Section constitutes aiding or abetting breach of fiduciary duty under state common law principles.

E. Defendants Promoted the Seroquel Franchise Using Various False and/or Misleading Messages, Misbranding the Products in Violation of Federal and State Law

1. Defendants Misrepresented Seroquel IR's Side Effect Profile, Misbranding the Product in Violation of Federal and State Law

103. One of the most common side effects associated with use of Seroquel IR is that of somnolence or sedation. Defendants and Defendants' sales representatives used various false and/or misleading promotional messages in an attempt to minimize concerns regarding this side effect, including, but not limited to:

- Claiming that sleep is beneficial and helps to re-establish mood-stabilization;
- Claiming that somnolence is part of the underlying disease (*i.e.*, bipolar disorder), and thus it is the underlying disease, not Seroquel IR, causing the somnolence;
- Claiming that to the extent Seroquel IR causes somnolence or sedation, it is only transient in nature and will dissipate; and
- Claiming that Seroquel IR helps to restore "sleep architecture."

104. Defendants' sales representatives in both the CNS and MCL sales teams delivered these promotional messages on numerous occasions to Texas healthcare providers, including providers participating in the Texas Medicaid program.

105. Any such attempts by Defendants to suggest that Seroquel IR's sedating qualities are actually caused by the underlying disease, are transient in nature, or are a benefit rather than a side effect, are false and/or misleading, and contrary to the FDA-approved labeling.

106. Furthermore, Defendants created new intended uses and/or disseminated false and/or misleading advertisements for Seroquel IR by promoting it for the purposes of causing

sedation to stabilize mood and restoring "sleep architecture," causing Seroquel IR to be misbranded in violation of federal and state law.

2. Defendants Misrepresented Seroquel XR's Side Effect Profile, Misbranding the Product in Violation of Federal and State Law

107. As Seroquel XR consists of the same active ingredient as Seroquel IR (quetiapine fumarate), somnolence is similarly one of XR's most frequent side effects. In an attempt to differentiate Seroquel XR from Seroquel IR at a time when the two drugs had identical indications, Defendants and Defendants' sales representatives disseminated false and/or misleading promotional messaging, including, but not limited to:

- Claiming that Seroquel XR had less sedation than Seroquel IR, including through the use of a "PK chart" and "Study 33";
- Claiming that proper dosing of Seroquel XR in the evening would eliminate issues of daytime sedation;
- Claiming that Seroquel XR has a "clean side effect profile"; and
- Claiming that Seroquel XR has fewer side effects than Seroquel IR.

108. Defendants' sales representatives in both the CNS and MCL sales teams delivered these promotional messages on numerous occasions to Texas healthcare providers, including providers participating in the Texas Medicaid program.

109. Any such attempts by Defendants to suggest that Seroquel XR's side effects, including its sedating qualities, are less than those caused by Seroquel IR (or are altogether non-existent), are false and/or misleading, and contrary to the FDA-approved labeling.

110. Furthermore, Defendants created a new intended use and/or disseminated false and/or misleading advertisements for Seroquel XR by promoting it for the purpose of being a

low-somnolence treatment option, causing Seroquel XR to be misbranded in violation of federal and state law.

3. Defendants Misrepresented Seroquel XR's Efficacy in Adjunctively Treating Major Depressive Disorder, Misbranding the Product in Violation of Federal and State Law

111. In December 2009, Defendants eventually gained a limited FDA approval for Seroquel XR for use as an adjunctive treatment to an antidepressant. Defendants launched Seroquel XR's adjunctive-MDD campaign in February 2010, transitioning all Seroquel XR promotion from bipolar depression to the new indication.

112. By 2010 there were a number of options for the treatment of MDD, including both older, generic drugs, such as tricyclic antidepressants, and newer drugs used adjunctively, such as Abilify.[46] In order to have a successful launch into this already-crowded market, Defendants recognized the need to differentiate their expensive drug from the established, often safer, therapeutic options. Defendants found the market's "unmet need" – the key to achieving success in this market – to exist in the concept of "remission."[47]

113. Within their 2010 Product Strategic Plan, Defendants planned to position Seroquel XR based on its efficacy in helping patients with MDD better achieve "remission." Following this high-level plan, Defendants' Brand Team developed a "remission" strategy statement to convey the brand positioning to the sales force. During Defendants' development of this "remission" strategy statement, the Senior Director of Clinical Development expressed concerns regarding the proposed language. In a January 2010 e-mail to the Brand Team, he wrote:

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[46] Other pharmacological options for treating MDD included MAOIs, SSRIs, SNRIs, and atypical antidepressants.

[47] As used by Defendants, "remission" in MDD occurs when a patient's total MADRS score is reduced to at most a level of eight after receiving treatment for their depression.

> However, I'm not thrilled about the phrase "proven to improve remission." In our promotional materials, the term "proven" is invariably followed by the FDA indication, e.g., proven effective in schizophrenia, bipolar depression, etc. With respect to studies 6 and 7, Seroquel XR was proven effective in MDD as adjunctive therapy to antidepressants. Remission was not the primary endpoint in the MDD trials…

The Brand Team dismissed these concerns without further consultation from the Senior Director of Clinical Development, and Defendants launched Seroquel XR's adjunctive MDD indication using the false and/or misleading "remission" strategy statement.

114. Secondary to remission, Defendants planned to promote Seroquel XR for use in the depressed patient experiencing the individual symptoms of sadness and loss of interest.

115. Defendants trained their CNS sales force to deliver the false and/or misleading "remission" and symptom-based patient profile messages, both in the February 2010 national launch meeting, and in later regional-level and district-level meetings. Defendants' sales force, in turn, executed the plan and delivered these false and/or misleading messages on thousands of sales calls to Texas healthcare providers, including to Texas Medicaid providers and decision makers. False and/or misleading "remission" messaging delivered to Texas healthcare providers included:

- Approximately 50% greater remission rates (MADRS Total Score ≤ 8) Seroquel XR plus an antidepressant vs an antidepressant alone at Week 6;
- In Study 6, Seroquel XR 300 mg/day + AD demonstrated significantly greater remission rates vs placebo + AD at Week 6 (42.5% vs 24.5%, respectively; $P<0.01$);
- In Study 7, Seroquel XR 150 mg/day + AD demonstrated significantly greater remission rates vs placebo + AD at Week 6 (36.1% vs 23.8%, respectively; $P<0.05$); and

- For these [Seroquel XR] studies, remission was defined conservatively as … MADRS Total Score ≤ 8 at Week 6.

False and/or misleading symptom-based patient profile messaging, on the other hand, involved describing a depressed patient who was still experiencing "sadness and loss of interest" despite being treated with an antidepressant. This patient profile was used by Defendants as an example of the type of patient for which a physician should prescribe Seroquel XR.

116. On or about February 26, 2010, Defendants' Neuroscience Field Physician delivered Defendants' false and/or misleading "remission" messages to the Texas Medicaid P&T Committee, on behalf of AstraZeneca, during public testimony. Following this hearing, the P&T committee recommended that Seroquel XR remain on the PDL.

117. Defendants promoted Seroquel XR in this manner until at least July 29, 2010, on which date FDA issued a letter to Defendants, informing Defendants that their promotional labeling relating to Seroquel XR's efficacy in achieving "remission" and in specifically addressing the individual symptoms of sadness and loss of interest as an adjunctive treatment in MDD was false and/or misleading, and caused the drug to be misbranded. According to the FDA letter, the "remission" claims were false and/or misleading because remission was neither a primary or key secondary measure in the referenced studies; six weeks was not sufficiently long to assess "remission"; and there is no regulatory definition of how to define "remission." For the individual symptom claims, FDA noted that Seroquel XR was only proven to reduce total MADRS scores, and that the clinical trials were not designed to assess Seroquel XR's impact on particular symptoms of MADRS.

118. By misrepresenting Seroquel XR's efficacy through the use of promotional labeling and advertisements that were false and/or misleading, and inconsistent with the FDA-

approved label, Defendants caused Seroquel XR to be misbranded in violation of federal and state law.

F. Defendants' Conduct Resulted in Harm to the State of Texas

119. Defendants' fraudulent and sophisticated marketing scheme targeting the Texas Medicaid program, based upon misrepresentations and omissions about Seroquel IR and Seroquel XR, resulted in excessive reimbursements for these drugs by the Texas Medicaid program. Specifically, as a result of Defendants' conduct, the Texas Medicaid program was prevented from making fully informed and appropriate policy decisions, and from utilizing the tools and safeguards available to the Medicaid program, including the VDP, DUR, and PDL processes, to appropriately manage the reimbursement of Seroquel IR and Seroquel XR prescriptions.

VIII. DEFENDANTS' VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION ACT

120. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 119 of this Petition.

A. Defendants' Violations of the TMFPA That Resulted in Harm to The State of Texas, and for Which Plaintiffs Seek Recovery and Civil Penalties

121. Defendants knowingly made or caused to be made false statements and/or misrepresentations of material facts to Texas Medicaid in applying for Seroquel XR's inclusion on the VDP formulary and during the PDL process. Furthermore, Defendants' false statements and/or misrepresentations permitted Defendants to receive benefits under the Medicaid program that were not authorized or that were greater than the benefits authorized, including, but not limited to, inclusion on the VDP formulary and virtually-unfettered reimbursement of Seroquel XR, in violation of the TMFPA. TEX. HUM. RES. CODE § 36.002 (1).

122. Defendants knowingly concealed or failed to disclose events or information from Texas Medicaid in conjunction with the VDP, DUR, and PDL processes. This conduct permitted Defendants to receive benefits under the Medicaid program, including, but not limited to, virtually unfettered reimbursement of Seroquel IR and Seroquel XR, that was not authorized or that was greater than the benefits authorized, in violation of the TMFPA. TEX. HUM. RES. CODE § 36.002 (2).

123. Defendants knowingly or intentionally made, or caused to be made, induced, or sought to induce the making of false statements and/or misrepresentations of material facts concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program in violation of the TMFPA. TEX. HUM. RES. CODE § 36.002 (4) (B).

124. As a result of Defendants' conduct, the Texas Medicaid program was prevented from making fully informed and appropriate policy decisions, and from fully utilizing the tools and safeguards available to the program, including the VDP, DUR, and PDL processes, to appropriately manage the reimbursement of Seroquel IR and Seroquel XR prescriptions. Defendants' illegal conduct, therefore, resulted in millions of dollars in excessive reimbursements for Seroquel IR and Seroquel XR by the State of Texas. Defendants' conduct additionally resulted in Defendants receiving the benefit of having Seroquel IR and Seroquel XR listed and maintained on the Texas Medicaid formulary during times when the drugs were in violation of federal and state law.

125. Under the TMFPA, each Defendant is liable to the State of Texas for the amount of any payments or the value of any monetary or in-kind benefits provided under the Medicaid program, directly or indirectly, as a result of its unlawful acts; two times the amount of those

payments or the value of the benefit; pre-judgment interest on the amount of those payments or the value of the benefit; and a civil penalty for each unlawful act committed, in addition to the fees, expenses, and costs of the State of Texas and the Relators in investigating and obtaining civil remedies in this matter. TEX. HUM. RES. CODE §§ 36.052, 36.007, 36.110 (c).

126. Plaintiffs invoke in the broadest sense all relief possible at law or in equity under TEX. HUM. RES. CODE § 36.052, whether specified in this pleading or not.

127. The amounts sought from each Defendant are in excess of the minimum jurisdictional limits of this Court.

128. The TMFPA is a statute of absolute liability. There are no statutory, equitable, or common law defenses for any violation of its provisions. Further, Texas jurisprudence provides that the defenses of estoppel, laches, and limitations are not available against the State of Texas as a Sovereign. *State v. Durham*, 860 S.W.2d 63, 67 (Tex. 1993).

B. Defendants' Violations of the TMFPA for Which Plaintiffs Seek Civil Penalties

129. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 128 of this Petition.

130. Under the TMFPA, Defendants are liable to the State of Texas for a civil penalty for each unlawful act committed by Defendants without regard to whether that violation resulted in harm. TEX. HUM. RES. CODE § 36.052.

131. Defendants' false and/or misleading messages regarding the safety, efficacy, and appropriate use of Seroquel IR and Seroquel XR were disseminated repeatedly to thousands of Texas Medicaid providers and decision makers. Each time that Defendants knowingly made, caused to be made, induced, or sought to induce the making of such false and/or misleading statements to a Texas Medicaid provider or decision maker concerning information required to

be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program, Defendants committed an unlawful act under the TMFPA. *See* TEX. HUM. RES. CODE § 36.002 (4) (B).

132. Defendants' widespread use of a false and/or misleading sales aid in 2010, described in detail in Paragraphs 111 – 118, *supra*, provides just one of numerous examples of such unlawful acts. Defendants' sales aid, which was characterized by the FDA as false and misleading based on its presentation of Seroquel XR remission data in MDD and the use of several individual symptoms of MDD, was utilized by Defendants' sales force during thousands of sales calls to Texas Medicaid providers and decision makers.

133. Defendants also knowingly made, caused to be made, induced, or sought to induce the making of false and/or misleading statements in violation of the TMFPA to Texas Medicaid providers and decision makers through journal publications, promotional materials, advisory boards, continuing medical education ("CME"), company-sponsored speeches, sales calls, and other means.

134. Additionally, Defendants knowingly engaged in conduct that constituted a violation under TEX. HUM. RES. CODE § 32.039 (b). *See* TEX. HUM. RES. CODE § 36.002 (13). By way of example, from 2008 to present, Defendants have paid over $465,000 to two doctors employed by the State of Texas. Defendants' internal e-mails reveal that these doctors were explicitly valued by Defendants for their influence within the state hospital system, including their ability to influence the placement of Seroquel XR on the DSHS formulary. Defendants also utilized these two state doctors to recommend the use of Seroquel XR to other healthcare providers, including to other state hospital doctors and healthcare providers participating in the Texas Medicaid program.

135. In furtherance of these objectives, Defendants offered or paid, directly or indirectly, overtly or covertly, remuneration, including kickbacks, bribes, or rebates, in cash or in kind to induce a person to purchase, lease, or order, or to arrange for or to recommend the purchase, lease, or order of, any good, facility, service, or item for which payment may be made, in whole or in part, under the medical assistance program. Defendants also provided or offered an inducement to a person, including a recipient, provider, or public servant, for the purpose of influencing a decision regarding: the use of goods or services provided under the medical assistance program, or the inclusion or exclusion of goods or services available under the medical assistance program. *See* TEX. HUM. RES. CODE § 32.039 (b).

136. Plaintiffs, therefore, seek civil penalties under the TMFPA for each of Defendants' unlawful acts under the TMFPA. Plaintiffs will seek an amount as civil penalties that will be justified and appropriate under the facts and the law.

IX. COMMON LAW FRAUD

137. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 136 of this Petition.

138. Defendants made representations of material facts, including, but not limited to, the certifications on the VDP applications, to the State of Texas that were false concerning the safety, efficacy, and appropriate use of Seroquel IR and Seroquel XR. Defendants knew such representations were false and/or made the representations recklessly, as a positive assertion, and without knowledge of their truth with the intent that the State of Texas act upon such representations. The State of Texas justifiably relied upon such representations, which caused injury and damages to the State of Texas.

139. Defendants also engaged in common law fraud by nondisclosure by failing to disclose material facts within their knowledge, which they had a duty to disclose, knowing that the Plaintiff State and Texas Medicaid decision makers were not aware of the concealed facts and did not have an equal opportunity to discover the truth. Defendants intended to induce the Plaintiff State and Texas Medicaid decision makers to take action by failing to disclose those facts. Plaintiff State has suffered injury as the result of acting without the knowledge of the undisclosed facts.

140. As a result of Defendant's conduct, Plaintiff State suffered harm and is entitled to recovery under common law fraud, including actual damages and prejudgment interest. Plaintiffs invoke in the broadest sense all relief possible at common law, whether specified in this pleading or not.

X. DEFENDANTS ACTIVELY ENCOURAGED OR ASSISTED FIDUCIARIES OF THE STATE TO BREACH THEIR FIDUCIARY DUTIES

141. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 140 of this Petition.

142. One or more Texas state mental health officials, as employees of the State of Texas, had a fiduciary duty with the State of Texas, including, but not limited to, the duty(ies) of good faith, fair dealing, loyalty, and/or fidelity owed to the State of Texas and its citizens.

143. Defendants provided substantial assistance to and/or aided, abetted, assisted, induced, or encouraged one or more Texas state mental health officials to breach their fiduciary duty(ies) owed to the State of Texas. Defendants knew that one or more Texas state mental health officials owed fiduciary duty(ies) to the State, yet Defendants executed consulting or other contracts that required services and imposed conditions upon those state employees that were at odds with and at times mutually exclusive to the duty(ies) owed to the State. Defendants also

provided inducements to the Texas state mental health official(s), including honoraria. For instance, as referenced in Paragraph 134, *supra*, from 2008 to present Defendants paid over $465,000 in honoraria to two state employees, as part of Defendants' Seroquel Franchise marketing efforts. The contracts, inducements, and other arrangements provided by the Defendants resulted in one or more Texas state mental health officials giving advice and making decisions that advanced the Defendants' financial interests ahead of the State's interests. Further, Defendants knew, or reasonably should have known, that their conduct would cause the Texas state mental health official(s) to breach their fiduciary duty(ies) to the State.

144. Plaintiff State of Texas, and the people and taxpayers of the State of Texas, suffered injury as a proximate result of Defendants' wrongful act(s).

XI. NEGLIGENT MISREPRESENTATION

145. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 144 of this Petition.

146. Defendants made misrepresentations to the Plaintiff State of Texas, including, but not limited to, the false certifications on the VDP applications, by and through its Texas state mental health decision makers and other officers and employees, in the course of the Defendants' business or transactions in which Defendants had pecuniary interests.

147. Defendants supplied information that was false for the guidance of others, and failed to exercise reasonable care or competence in obtaining or communicating the information.

148. Plaintiff State, by and through its state mental health decision makers, officers and employees, justifiably relied on the misrepresentations.

149. Defendants' negligent misrepresentations proximately caused Plaintiff State's injuries, including pecuniary loss.

XII. MONIES HAD AND RECEIVED

150. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 149 of this Petition.

151. Plaintiff State, unaware of Defendants' wrongdoing and unlawful acts, paid excessive Medicaid reimbursements that would otherwise not have been allowed.

152. Defendants hold money that in equity and good conscience belongs to the Plaintiff State, and retention of those funds by any of Defendants would be inequitable and unjust in this case.

153. Defendants should be required to disgorge to Plaintiff State the revenue wrongfully and unlawfully obtained from Seroquel IR and Seroquel XR sales ultimately reimbursed under the Texas Medicaid program.

154. The State demands that judgment be entered against Defendants in an undetermined amount for unjust enrichment, restitution of monies gained by the Defendants, interest and costs of suit, including attorney's fees and all such other relief at law and equity to which the State of Texas is entitled.

155. By reason of the overpayments described above, the State of Texas is entitled to damages in an amount to be determined at trial exclusive of interest and costs.

XIII. PROMISSORY ESTOPPEL

156. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 155 of this Petition.

157. Defendants entered into a contractual promise with the State during the VDP application process. During this process, Defendants certified their products' compliance with federal and state laws. Defendants additionally agreed to update the State as to any changes,

inter alia, in product status. As a result of this promise, Defendants' products Seroquel IR and Seroquel XR were added to, and/or maintained on, the VDP formulary.

158. The State, through VDP, reasonably and substantially relied on Defendants' promise to its detriment.

159. Defendants could have foreseen the State's reliance on the promise, since Texas State law requires the submission of truthful information during the VDP application process.

160. Injustice can be avoided only by enforcing the Defendants' promise to comply with federal and state laws.

161. By reason of the State's reliance on Defendants' promise, described above, the State of Texas is entitled to damages in an amount to be determined at trial.

XIV. REMEDIES FOR COMMON LAW CAUSES OF ACTION

162. As a result of Defendants' conduct, to wit: common law fraud, negligent misrepresentation, wrongfully receiving and retaining funds rightfully belonging to the Plaintiff State of Texas, and promissory estoppel as a claim, Plaintiff State suffered harm as a proximate result of that conduct, and are entitled to recovery including actual damages, prejudgment interest, post-judgment interest, disgorgement, restitution for the value of all payments that the State has made for Seroquel IR and Seroquel XR prescriptions reimbursed under the Texas Medicaid program, and other legal and equitable relief as the court may determine appropriate. Plaintiffs invoke in the broadest sense all relief possible at common law, whether specified in this pleading or not.

XV. STATUTORY INJUNCTION UNDER § 36.051 OF THE ACT

163. The Attorney General has good reason to believe the Defendants are committing, have committed, or are about to commit unlawful acts as defined by the TMFPA. These illegal acts may be enjoined under § 36.051 of the TMFPA.

XVI. JURY DEMAND

164. Plaintiffs respectfully request a trial by jury on all claims pursuant to Texas Rules of Civil Procedure 216.

XVII. PRAYER

165. Plaintiffs ask that judgment be entered upon trial of this case in favor of the State and the Relators against Defendants to the maximum extent allowed by law.

166. Plaintiffs ask for injunctive relief pursuant to § 36.051 of the TMFPA.

167. The State of Texas asks that it recover from Defendants under all applicable Texas common law principles:

A. its reasonable damages as they may appear at trial;

B. punitive or exemplary damages;

C. forfeiture and disgorgement of Defendants' revenues from Seroquel IR and Seroquel XR sales in Texas in connection with Seroquel IR and Seroquel XR use in the Texas Medicaid population;

D. restitution, under the principle of unjust enrichment, of all proceeds improperly gained by Defendants as a result of Defendants' wrongful acts, via the imposition of a constructive trust on Defendants' revenue from Seroquel IR and Seroquel XR sales in Texas in connection with Seroquel IR and Seroquel XR use in the Texas Medicaid population;

E. prejudgment interest and interest on the judgment; and

F. such other and further relief to which it may show itself entitled, either at law or in equity, exclusive of interest and costs.

168. The State of Texas asks that it recover from Defendants under the TMFPA:

A. restitution of the amount of any payments or the value of any monetary or in-kind benefits provided under the Texas Medicaid program, directly or indirectly, as a result of Defendants' unlawful acts;

B. two times the amount of any payments or the value of any monetary or in-kind benefits provided under the Medicaid program, directly or indirectly, as a result of Defendants' unlawful acts;

C. civil penalties in an amount not less than $1,000 or more than $10,000 for each unlawful act committed by Defendants before May 4, 2007; in an amount not less than $5,000 or more than $10,000 for each unlawful act committed by Defendants on or after May 4, 2007 and prior to September 1, 2011; and in an amount not less than $5,500 or more than $11,000 for each unlawful act committed by Defendants on or after September 1, 2011.

D. prejudgment interest;

E. expenses, costs, and attorneys' fees; and

F. post-judgment interest at the legal rate.

169. Plaintiffs seek monetary relief in excess of $1,000,000.

170. The Relators asks that they be awarded:

A. expenses, costs and attorneys' fees;

B. Relator's share as provided by the TMFPA; and

C. Such other and further relief to which Relators may show themselves entitled, either at law or in equity.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify a true and correct copy of the foregoing Plaintiffs' First Amended Petition (filed under seal) has been sent via **electronic mail** on October 7, 2014 to:

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of Travis County, Texas

OCT -8 2014

At 2:12p M.
Amalia Rodriguez-Mendoza, Clerk

CAUSE NO. D-1-GN-13-003530

STATE OF TEXAS *ex rel.* [UNDER SEAL]	§	IN THE DISTRICT COURT
Plaintiffs,	§	
v.	§	353RD JUDICIAL DISTRICT
[UNDER SEAL]	§	
Defendants.	§	TRAVIS COUNTY, TEXAS

AGREED ORDER LIFTING AND REMOVING SEAL AND ALLOWING SERVICE OF PROCESS UPON DEFENDANTS

CAME ON THIS DAY to be heard in the above-numbered and styled cause the unopposed *ex parte* Motion to Unseal previously filed by the State of Texas. The Court, having considered said Motion finds it to be well taken and rules that it should be GRANTED in all respects. It is therefore:

ORDERED that as of October 8, 2014, the seal in this *qui tam* matter should be and hereby is lifted and removed with respect to the Plaintiffs' First Amended Petition, and it is further:

ORDERED that service of process should be and hereby is permitted to be prepared and served upon all Defendants, requiring them to answer herein.

SIGNED this 8th day of October, 2014.

JUDGE PRESIDING

TIM SULAK

AGREED:

JONATHAN D. BONILLA
Assistant Attorney General
Attorney for the State of Texas

James Pepper (By Permission)
JAMES J. PEPPER
Attorney for Plaintiff/Relator Allison Zayas

W. Scott Simmer (By permission)
W. SCOTT SIMMER
Attorney for Plaintiff/Relator Tracy Miksell-Branch

CAUSE NO. D-1-GN-13-003530

STATE OF TEXAS *ex rel.* [UNDER SEAL]	§	IN THE DISTRICT COURT
Plaintiffs,	§	
v.	§	353RD JUDICIAL DISTRICT
[UNDER SEAL]	§	
Defendants.	§	TRAVIS COUNTY, TEXAS

AGREED ORDER LIFTING AND REMOVING SEAL AND ALLOWING SERVICE OF PROCESS UPON DEFENDANTS

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SIGNED this 8th day of October, 2014.

JUDGE PRESIDING
TIM SULAK

ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

October 15, 2014

Via Electronic Filing
Ms. Amalia Rodriguez-Mendoza
Travis County District Clerk
1000 Guadalupe, Room 302
Austin, Texas 78701

Re: *The State of Texas ex rel. Allison Zayas and Tracy Miksell-Branch v. AstraZeneca, L.P., AstraZeneca Pharmaceuticals, L.P., AstraZeneca Biopharmaceuticals, Inc. and AstraZeneca PLC*; Cause No. D-1-GN-13-003530, 353rd District Court, Travis County, Texas

Dear Ms. Rodriguez-Mendoza:

This letter will serve as a formal request for preparation of an original and one copy of each of the Citations for the defendants listed below in the above-referenced cause number:

1. AstraZeneca, L.P.
c/o Registered Agent
C T Corporation System
1999 Bryan Street, Suite 900
Dallas, Texas 75201-3136

2. AstraZeneca Pharmaceuticals, L.P.
c/o Registered Agent
C T Corporation System
1999 Bryan Street, Suite 900
Dallas, Texas 75201-3136

3. AstraZeneca Biopharmaceuticals, Inc.
c/o Registered Agent
C T Corporation System
1999 Bryan Street, Suite 900
Dallas, Texas 75201-3136

4. AstraZeneca PLC
2 Kingdom Street
London W2 6BD
UK

Our office will be serving the citations by private process. Please notify my legal assistant, Jennifer Rowell, at 512-936-1586, and she will arrange for the couriers from our office to pick them up for processing.

If you have any questions, please do not hesitate to call me at the number listed below or my legal assistant. Thank you for your cooperation in this matter.

Sincerely,

Eugenia L. Krieg
Assistant Attorney General
Civil Medicaid Fraud Division
(512) 936-1937
(512) 499-0712 [Fax]

ATTORNEY GENERAL OF TEXAS

GREG ABBOTT

October 29, 2014

Via Regular Mail & Electronic Mail
John C. Dodds
Morgan Lewis
1701 Market Street
Philadelphia, PA 19103-2921
jdodds@morganlewis.com

Re: *State of Texas, ex rel. Zayas et al. v. AstraZeneca, L.P. et al.*, District Court, 353rd Judicial District, Travis County, Texas, Cause No. D-1-GN-13-003530; RULE 11 AGREEMENT

Dear Jack,

This letter is to memorialize our agreement regarding service of process upon the Defendants in the above-referenced matter, as well as other related items.

You have told me that you are authorized to accept service of process on behalf of AstraZeneca, LP ("AZLP") and AstraZeneca Pharmaceuticals, L.P. ("AZPLP"). A copy of Plaintiffs' First Amended Petition was sent electronically via e-mail from Raymond Winter to you and Michael Moore on October 10, 2014. It is agreed that you have not accepted service of process for the First Amended Petition. Additionally, service of process has not been effectuated on AZLP, AZPLP, or any of the other Defendants named in the First Amended Petition.

With regard to AstraZeneca PLC ("PLC") and AstraZeneca Biopharmaceuticals, Inc. ("AZB"), we agree that Plaintiffs will not serve PLC or AZB, and that Plaintiffs will file their Second Amended Petition, which will non-suit PLC and AZB, within 20 days from the date of this agreement. As part of the agreement to non-suit these entities, you represent and affirm, by your signature below, that you have reviewed the First Amended Petition and have the authority and legal power to enter into this agreement on behalf of AZLP, AZPLP, PLC and AZB.

It is agreed that you will accept service of the Second Amended Petition on behalf of AZLP and AZPLP, and waive formal service of the same. Your acceptance of service for AZLP and AZPLP is without waiver of any defense. It is agreed that the service date for the Second Amended Petition will be the date on which you receive an electronic copy of the Second Amended Petition via e-mail from the Office of the Attorney General (the "Service Date"). Any applicable state or federal deadlines, including but not limited to responsive pleading and removal deadlines, will begin to run on the Service Date.

You further represent and affirm that in the event Plaintiffs attain judgment against AZLP and/or AZPLP in the above-referenced matter: AZLP and/or AZPLP will not avoid, or attempt to avoid, partial or total payment or satisfaction by contending that PLC's or AZB's status as a non-defendant prevents AZLP or AZPLP from satisfying the judgment; or that AZLP or AZPLP

cannot satisfy any part of said judgment without PLC's or AZB's consent; or that some or all of the funds necessary to satisfy such judgment must be obtained from PLC or AZB. The defendants assert that AZLP, AZPLP, PLC and AZB are separate corporate entities and nothing contained herein shall impair or impact their right to assert such.

You further represent and affirm that to the extent that discovery in the above-referenced case, including without limitation discovery adduced from AZLP or AZPLP, suggests some relevant and non de minimus involvement by PLC or AZB in the issues implicated in this matter, PLC and AZB agree that any discovery requests and/or subpoena or deposition notices Plaintiffs may direct to PLC or AZB may be served through then-counsel for AZLP or AZPLP, as if PLC and/or AZB were named parties in the above-referenced matter, without the need to serve any such requests through any other method of personal service, and without the need to comply with Texas Rules of Civil Procedure 205 or 191.4(b) concerning discovery from non-parties. In such event, Plaintiffs agree that PLC and AZB retain and reserve all other rights regarding objections and defenses to such requests, notices or subpoenas.

The undersigned further agree that other than to enforce the terms of this agreement, the parties shall use nothing in this agreement in any way in the above-referenced matter. This agreement shall not operate as an admission or indication of any element or basis of any claim against any party nor will this agreement operate as an admission. Neither this agreement nor any action taken pursuant to this agreement shall be offered or received in evidence in any action or proceeding as an admission of liability by any party, wrongdoing by any party, suggestion that a claim lacks merit, or any element or basis of any claim against any party.

If this letter correctly outlines our agreement and your clients are agreeable to these terms, please sign below and return this letter to me.

Sincerely,

Date: 10/29/14

Eugenia La Fontaine Krieg
Assistant Attorney General
Office of the Attorney General
Civil Medicaid Fraud Division

Attorney for the State of Texas

AGREED TO AND APPROVED:

John C. Dodds

Date: 10/30/14

John C. Dodds, Esquire
Morgan, Lewis & Bockius LLP

Attorney for AstraZeneca Pharmaceuticals, L.P., AstraZeneca L.P., AstraZeneca PLC and AstraZeneca Biopharmaceuticals, Inc.

cc: James J. Pepper (via electronic mail)
W. Scott Simmer (via electronic mail)

11/14/2014 4:36:43 PM
Amalia Rodriguez-Mendoza
District Clerk
Travis County
D-1-GN-13-003530

CAUSE NO. D-1-GN-13-003530

THE STATE OF TEXAS, *ex rel.* **ALLISON ZAYAS and TRACY MIKSELL-BRANCH,**	§	**IN THE DISTRICT COURT**
Plaintiffs,	§	**353d JUDICIAL DISTRICT**
v.	§	
ASTRAZENECA, L.P., and ASTRAZENECA PHARMACEUTICALS, L.P.	§	**TRAVIS COUNTY, TEXAS**
Defendants.	§	

PLAINTIFFS' SECOND AMENDED PETITION

The State of Texas, by and through the Attorney General of Texas, Greg Abbott, ("the State") and Private Person Plaintiff/Relators Tracy Miksell-Branch ("Relator Miksell-Branch") and Allison Zayas ("Relator Zayas") (collectively, "Relators") bring this law enforcement action pursuant to the Texas Medicaid Fraud Prevention Act ("TMFPA"), TEX. HUM. RES. CODE Chapter 36, and common law. Plaintiffs, the State and Relators, file this Second Amended Petition ("Petition") and would respectfully show the Court as follows:

I. DISCOVERY CONTROL PLAN

1. Discovery is intended to be conducted under Level 3 of Rule 190, Texas Rules of Civil Procedure.

II. PRELIMINARY STATEMENT AND NATURE OF THIS ACTION

2. This is a law enforcement action under the TMFPA and common law to recover taxpayer dollars spent as a result of AstraZeneca's fraudulent conduct. Specifically, AstraZeneca targeted Texas Medicaid with a fraudulent marketing scheme for its expensive and powerful

atypical antipsychotic drugs Seroquel (herein "Seroquel IR") and Seroquel XR. Under this scheme, AstraZeneca disseminated false and/or misleading messages during thousands of sales calls to doctors and other healthcare practitioners who were enrolled Texas Medicaid providers, including: 1) false and/or misleading messaging relating to the drugs' efficacy in unapproved conditions; 2) false and/or misleading messaging intended to downplay certain side effects; and 3) false and/or misleading messaging concealing the potent nature of these drugs. Additionally, AstraZeneca promoted Seroquel IR and Seroquel XR for unapproved use in the vulnerable pediatric population. Further, as part of their marketing plan to drive sales for Seroquel IR and Seroquel XR, AstraZeneca unduly influenced and improperly exploited Texas state officials to facilitate their misrepresentations. This illegal conduct caused Seroquel IR and Seroquel XR to be in violation of federal and state law, and rendered false AstraZeneca's sworn certifications of compliance to Texas Medicaid, which are required for drugs to be listed on the Texas Medicaid formulary. As a result, AstraZeneca obtained the benefit of virtually unfettered Medicaid reimbursements for Seroquel IR and Seroquel XR on the basis of fraudulent and unlawful misrepresentations, and in so doing, AstraZeneca violated the TMFPA and Texas common law.

III. THE PARTIES

A. Plaintiffs

3. The Plaintiffs are the State of Texas, by and through the Attorney General of Texas, Greg Abbott, ("the State") and relators Tracy Miksell-Branch and Allison Zayas (collectively, "Plaintiffs").

4. Relator Tracy Miksell-Branch is a citizen of the United States and a resident of Iowa. From November 2000 until May 2010, Relator Miksell-Branch worked as an Executive Pharmaceutical Sales Specialist (EPSS) in AstraZeneca's Central Nervous System ("CNS")

division, where her primary duties and responsibilities entailed marketing Seroquel IR, and later, Seroquel XR. Through her employment at AstraZeneca as an EPSS, Relator Miksell-Branch gained a wealth of direct and independent knowledge of the fraudulent schemes perpetrated by the Defendants. Relator Miksell-Branch witnessed meetings and discussions related to AstraZeneca's schemes to maximize sales of Seroquel IR and Seroquel XR through means that included influencing, manipulating, and making misrepresentations to psychiatrists, pharmacists, and other health care professionals.

5. Relator Miksell-Branch resigned from AstraZeneca on May 10, 2010, as a result of threats, harassment, and other retaliation that she suffered after AstraZeneca disclosed to her regional and district managers, as well as to sales representatives in her district, that Relator Miksell-Branch had reported the Company's ongoing, illegal off-label promotion of Seroquel IR and Seroquel XR to AstraZeneca's compliance department. Relator Miksell-Branch also wished to disassociate herself from AstraZeneca's continuing illegal conduct.

6. Relator Allison Zayas is a citizen of the United States and a resident of New York. From May 2006 until November 2010, Relator Zayas was a Pharmaceutical Sales Specialist ("PSS") in AstraZeneca's CNS division, where her primary duties and responsibilities entailed marketing Seroquel IR, and later, Seroquel XR. Because of her position, Relator Zayas has unique knowledge of the sales and marketing efforts behind both Seroquel IR and Seroquel XR. Furthermore, because of her position, Relator Zayas has unique knowledge of how AstraZeneca unlawfully promoted Seroquel IR and Seroquel XR.

7. Relators originally provided information to the State of Texas, which is the basis for this suit. Relators filed their Original Petitions under seal, pursuant to the authority granted by TEX. HUM. RES. CODE § 36.101, alleging Defendants' false statements, misrepresentations,

and concealment of material information violated the TMFPA, TEX. HUM. RES. CODE § 36.001 *et seq*. Relators' allegations were based on their direct, independent, and personal knowledge and also on information and belief. Relators are original sources of the information underlying this Second Amended Petition and provided such information to the State of Texas in their Disclosure Statements. Relators' Disclosure Statements presented substantially all material evidence and information they had in their possession at the time of the filing of their Original Petitions pursuant to TEX. HUM. RES. CODE § 36.102. Prior to filing her Original Petition, Relator Miksell-Branch brought the wrongdoing described herein to the attention of AstraZeneca.

B. Defendants

8. Defendant ASTRAZENECA, L.P. ("AstraZeneca L.P.") is a limited partnership organized under the laws of Delaware and has its principal place of business in Delaware, at 1800 Concord Pike, Wilmington, DE 19850. AstraZeneca L.P. marketed and distributed the drugs Seroquel IR and Seroquel XR in Texas. AstraZeneca L.P. conducts business in Texas.

9. Defendant ASTRAZENECA PHARMACEUTICALS, L.P. ("AstraZeneca Pharmaceuticals") is a limited partnership organized under the laws of Delaware and has its principal place of business in Delaware, at 1800 Concord Pike, Wilmington, DE 19850. AstraZeneca Pharmaceuticals marketed and distributed the drugs Seroquel IR and Seroquel XR in Texas. AstraZeneca Pharmaceuticals conducts business in Texas.[1]

IV. JURISDICTION AND VENUE

10. This Court has jurisdiction of this action pursuant to TEX. HUM. RES. CODE § 36.101. Venue is proper in Travis County and this judicial district pursuant to TEX. HUM. RES.

[1] AstraZeneca L.P. and AstraZeneca Pharmaceuticals are collectively referred to herein as "Defendants" or "AstraZeneca."

CODE § 36.052 (d). Moreover, the unlawful acts and omissions described herein occurred, in substantial part, in Travis County. Consequently, venue is proper in Travis County pursuant to TEX. CIV. PRAC. & REM. CODE § 15.002 (a) (1). Jurisdiction is further proper because the amounts sought from each Defendant exceed the minimum jurisdictional limits of this Court.

V. BACKGROUND

A. Atypical Antipsychotics and Associated Safety Risks

11. Second-generation antipsychotics, more commonly referred to as atypical antipsychotics ("atypicals"), are powerful drugs that were developed in the early 1990s as alternatives to first-generation or "conventional" antipsychotics for the treatment of serious and debilitating mental disorders, such as schizophrenia and bipolar disorder. In part as a result of their manufacturers' extraordinary – and often illegal – marketing efforts to portray the atypicals as safer, more effective, and appropriate for broader use than the similarly effective conventional antipsychotics, atypicals now account for about 90% of all antipsychotic prescriptions, despite many of those brand-name drugs being vastly more expensive than conventional antipsychotics.[2]

12. The perception that second generation antipsychotics are safe – more so than they actually are – has contributed to the increase in the prescribing of atypicals for a litany of off-label conditions, including: agitation; aggression; anxiety and generalized anxiety disorder ("GAD"); behavioral disorders, including ones related to dementia; obsessive compulsive disorder; major depressive disorder ("MDD") as monotherapy; post-traumatic stress disorder ("PTSD"); and personality disorders. The use of atypicals in these off-label conditions is unproven to be superior to placebo, and in some cases, is actually counter-productive to patient

[2] Patent exclusivity is the main driver of price for drugs in this class. Risperdal lost exclusivity in 2008; Zyprexa in 2011; Geodon, Seroquel IR, and Invega in 2012. Abilify and Seroquel XR continue to enjoy patent protection.

recovery.

13. Further, off-label atypical use in the child and adolescent population is also large and continues to grow. From 2004 to 2008, pediatric prescriptions of atypical antipsychotics dispensed by retail pharmacies increased from 3.94 to 4.8 million and accounted for 9% of all Seroquel IR prescriptions.[3] Children in the foster care system[4] have been particularly impacted by the trending increase in atypical usage. For example, in 2009, over 21% of foster children in Texas received at least one atypical (and oftentimes, multiple atypicals) for sixty days or more, a rate that was ten times higher than the national rate for non-foster children with Medicaid, and twenty times higher than the national rate for non-foster children with private insurance.

14. The perception that atypical antipsychotics are "safer" than conventional antipsychotics, however, does not mean that atypicals are actually safe for the broad array of uses for which they have been marketed. On the contrary, use of atypicals, including Seroquel IR and Seroquel XR, is accompanied by the risk of numerous adverse events, among the most serious of which are: metabolic abnormalities that may lead to diabetes and weight gain; cardiac disorders; debilitating movement disorders; and cognitive impairment. In addition, use of each drug is accompanied by significant risks of hypotension, elevated liver enzymes (an indicator of liver damage), abdominal pain, constipation, dizziness, somnolence, and a litany of other cardiac,[5] digestive, musculoskeletal, and nervous system adverse events, including sudden death. These serious side effects can be particularly dangerous in the vulnerable pediatric and elderly

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[3] At no point during this 2004-2008 time period did Seroquel IR have an indication for use in the child and adolescent population, thus making such use off-label.

[4] In Texas, the majority of foster children automatically qualify for Medicaid coverage.

[5] A study published in 2009 in the New England Journal of Medicine found that patients taking Seroquel and other atypicals experienced a risk of sudden cardiac death that was more than double that of the ordinary population. Ray, et al., *Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death*, 360 New Eng. J. Med. 225 (2009).

populations. A recent study published in the *American Academy of Child and Adolescent Psychiatry* underscores the potential health risks of antipsychotic therapy, finding that the rate of developing diabetes more than doubled for children and adolescents who received antipsychotic therapy.[6] As well, the product labels for both Seroquel IR and Seroquel XR contain a black box warning that elderly patients with dementia-related psychosis who take either drug are at an increased risk for death.

15. As recognized by an FDA Advisory Committee convened to consider expanding the approved uses of Seroquel XR, whether a patient's exposure to Seroquel XR's significant risks is justified depends both on the seriousness of the disease being treated as well as the availability of alternative, safer therapies. For patients with the most serious psychiatric diseases, such as schizophrenia and bipolar disorder, the risks of experiencing these adverse events may be justified. However, for other more common and less severe conditions, the efficacy benefit may be too small or uncertain to justify the risks. Indeed, Seroquel XR's side effect profile was critical to the FDA's determination to *not* approve Seroquel XR for treatment of GAD, and to *not* approve Seroquel XR as monotherapy to treat MDD; the FDA concluded that the demonstrated efficacy benefit was insufficient to balance Seroquel XR's known risks, particularly given the availability of other, safer treatments for these conditions.

B. Seroquel IR's FDA-Approved Indications

16. Seroquel IR is an atypical antipsychotic originally approved by the FDA in September 1997 for the acute treatment of schizophrenia in adult patients.

17. In January 2004, the FDA approved Seroquel IR for "short-term treatment of

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[6] Nielsen, et al., *Risk of Diabetes in Children and Adolescents Exposed to Antipsychotics: A Nationwide 12-Year Case-Control Study*, 53.9 J. Am. Acad. Child Adolesc. Psychiatry 971 (2014).

acute manic episodes associated with bipolar I disorder, as either monotherapy[7] or adjunct therapy[8] to lithium or divalproex" in adult patients.

18. On October 20, 2006, the FDA approved Seroquel IR for the treatment of depressive episodes associated with bipolar disorder in adult patients.

19. On December 2, 2009, the FDA approved Seroquel IR as treatment for schizophrenia in 13- to 17-year-old adolescents, and for the acute treatment of manic episodes associated with bipolar I disorder in 10- to 17-year-old children and adolescents. These very limited approvals were the only indications that Seroquel IR received for the treatment of children and adolescents. The FDA has never approved Seroquel IR for use in children under the age of 10.

20. At no point in time has FDA approved – or has AstraZeneca sought approval for – Seroquel IR to treat Major Depressive Disorder, either as a monotherapy or as an adjunctive therapy to an antidepressant.

C. **Seroquel XR's FDA-Approved Indications**

21. On May 17, 2007, the FDA approved Seroquel XR for the acute treatment of schizophrenia in adult patients. Defendants made Seroquel XR available for sale in the United States shortly thereafter in July 2007. On November 15, 2007, the FDA extended Seroquel XR's approval for maintenance treatment of schizophrenia in adult patients.

22. On October 8, 2008, the FDA approved Seroquel XR in adult patients as monotherapy for the acute treatment of the depressive episodes associated with bipolar I and bipolar II disorders; as monotherapy for acute treatment of manic and mixed episodes associated

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7 Monotherapy is the use of a single drug to treat a particular disorder or disease.

8 Adjunct therapy is the use of another treatment, in conjunction with the primary treatment, to assist the primary treatment.

with bipolar I disorder; and as maintenance treatment for bipolar I disorder as adjunctive therapy to lithium or Depakote (divalproex sodium).

23. In February 2008, Defendants submitted a supplemental New Drug Application ("sNDA") to the FDA seeking approval of Seroquel XR to treat MDD as a monotherapy, adjunct therapy, and maintenance therapy. The FDA Advisory Committee determined that Seroquel XR was insufficiently safe for most of these uses and, on December 2, 2009, the FDA refused to approve Seroquel XR for broad use in treating MDD. The FDA limited its approval of Seroquel XR in MDD to adjunctive use to an antidepressant in patients who had an inadequate response to an antidepressant alone.

24. In May 2008, Defendants submitted an sNDA seeking approval of Seroquel XR to treat generalized anxiety disorder ("GAD"). The same FDA Advisory Committee that considered the MDD application also considered the GAD application and concluded that Seroquel XR was not safe for the treatment of GAD. The FDA followed the Advisory Committee's recommendation and refused to approve Seroquel XR for the treatment of GAD.

25. On April 30, 2013, the FDA approved Seroquel XR for two very limited groups within the child and adolescent population: the treatment of schizophrenia in 13- to 17-year-old adolescents; and the acute treatment of manic episodes associated with bipolar I disorder in 10- to 17-year-old children and adolescents. As with Seroquel IR, Seroquel XR has never been FDA-approved for use in children younger than 10.

D. The FDA Regulatory System

1. The Role of the FDA in Regulating Prescription Drug Promotion

26. In the United States, the sale and promotion of prescription drugs is regulated by the U.S. Food and Drug Administration ("FDA"), pursuant to the authority granted by the

Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. Under the FDCA, new drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the FDA "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof."[9,10] As well, the drug's sponsor must show by substantial evidence that the drug is safe for the conditions of use "prescribed, recommended, or suggested in the proposed labeling."[11] Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

27. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any clinical investigations itself. Applications for FDA approval of pharmaceutical products (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use."[12]

28. The FDCA requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness.[13] The FDA approves a drug if there are adequate and well-controlled clinical trials that demonstrate a drug's safety and effectiveness for its intended conditions of use.[14] Importantly, the FDA's determination of a drug's "safety" consists of a risk-benefit analysis that includes consideration of the severity of conditions for which the drug's approval is sought, as well as the other available treatments for such conditions.[15]

29. Once the FDA has approved a drug's NDA for a specific condition – an

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9 21 U.S.C. § 355 (d) (5).
10 "Substantial evidence," as used in this section, is defined at 21 U.S.C. § 355 (d) (7).
11 21 U.S.C. § 355 (d) (1).
12 21 U.S.C. § 355 (b) (1) (A).
13 *See* 21 U.S.C. § 355 (d) (7).
14 *See* 21 U.S.C. § 355 (d) (5).
15 *See* 21 U.S.C. § 355 (d) (7).

"indication for use" in FDA terminology – the drug's sponsor is legally only authorized to promote the drug for that particular indication.[16] In order to expand an approved drug's indications for use under the FDCA, the sponsor must submit – and FDA must approve – a supplemental New Drug Application ("sNDA") for each new intended use. In evaluating an sNDA, the FDA applies the same statutory standards for safety and effectiveness as with the original NDA, including carefully balancing the drug's risks and benefits for the new potential indication for use.[17]

2. FDA Regulations Prohibit the Misbranding of Prescription Drugs

30. Under the FDCA, it is illegal to introduce into interstate commerce any drug that is misbranded.[18] A drug is misbranded if the labeling is false or misleading in any particular, the labeling does not contain adequate directions for use, or the manufacturer utilizes false or misleading advertisements relating to the drug.[19]

31. "Labeling" is a core concept of pharmaceutical regulation within the FDCA, and is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[20] Courts have interpreted labeling broadly to encompass printed material even when not physically attached or connected to the related pharmaceutical product.[21]

32. Pursuant to the authority granted by the FDCA, the FDA promulgated a series of

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16 Promotion of a drug for a non-indicated use is commonly referred to as "off-label promotion," and can serve as evidence that the drug's manufacturer created a new intended use for the drug. *See* Section V.D.2, *infra*.

17 *See* 21 U.S.C. § 355 (d) (7).

18 21 U.S.C. § 331 (a).

19 21 U.S.C. § 352 (a), (f), (n).

20 21 U.S.C. § 321 (m).

21 *See Kordel v. United States*, 335 U.S. 345 (1948).

regulations further expanding on the drug-related statutory requirements of the FDCA.[22] Under these regulations, 21 C.F.R. 201.5 defines "adequate directions for use" to mean "directions under which the layman can use a drug safely and for the purposes for which it is intended. (Section 201.128 defines "intended use.")." For prescription drug products that require the supervision of a medical professional to safely administer, 21 C.F.R. 201.100 clarifies that product labeling must contain "adequate information for such use ... under which practitioners licensed by law to administer the drug can use the drug safely *and for the purposes for which it is intended, including all conditions for which it is advertised or represented.*" (Emphasis added).

33. "Intended use" is defined by 21 C.F.R. 201.128 as referring "to the objective intent of the persons legally responsible for the labeling of drugs." Intended use "is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article." Furthermore, "this objective intent may ... be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." Intended use can also be shown circumstantially.

34. The FDA requires pre-approval of changes to prescription drug labels.[23] Thus, a manufacturer that creates a new "intended use" for its prescription drug product cannot unilaterally amend the label to include this new intended use;[24] rather, the drug will necessarily be misbranded at that point in time, in violation of the FDCA.

35. In sum, the misbranding regulatory regime protects patients and consumers by

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22 *See* 21 C.F.R. 200-369.

23 *See* 21 C.F.R. 314.50, 314.70. This provision does not apply to a drug company unilaterally adding newly-discovered drug safety information to the label. *Wyeth v. Levine*, 555 U.S. 555, 567 (2009).

24 As discussed in Section V.D.1, *supra*, FDA requires "substantial evidence" of efficacy and safety, in the form of well-controlled clinical trials, for a new intended use to be approved for a drug.

ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body – the FDA. Moreover, the prohibition on false or misleading labeling claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on deceptive marketing tactics.

3. **The Limited Role of the FDA in Regulating Prescription Drug Promotion**

36. The FDA's Office of Prescription Drug Promotion[25] ("OPDP") is charged with overseeing the marketing and promotion of approved drugs to ensure that drug promotion: (a) is not false or misleading; (b) provides a fair balance between the benefits and risks of the drug; and (c) does not misbrand the drug. *See* Statement by Janet Woodcock, M.D., Director Center for Drug Evaluation and Research, FDA, Before the Senate Special Committee on Aging (July 22, 2003).

37. OPDP's ability to regulate misbranding is limited. In 2003, its entire staff consisted of 40 members, with 25 reviewers responsible for reviewing all drug advertisements and promotional materials.

38. Moreover, materials promoting pharmaceutical products do not have to be pre-approved. FDA review of promotional materials occurs, if it does at all, after the materials have already appeared in public. *See* Woodcock Statement, *supra*. Upon finding a violation, OPDP generally requests the company to stop using the violative promotional materials. *Id.* OPDP occasionally requires sponsors to publicly correct product misimpressions created by materials that are false, misleading, and/or lacking in fair balance. *Id.*

E. **Defendants Specifically Targeted the Texas Medicaid Program**

39. Schizophrenic adults represent less than one percent (1%) of the United States

[25] Formerly known as the Division of Drug Marketing, Advertising, and Communications (DDMAC).

population, while estimates of adults with bipolar disorder range from two percent (2%) to three percent (3%). Adults with severe mental illness such as schizophrenia and bipolar disorder are more likely to be uninsured, unemployed, impoverished, and therefore, unable to afford Seroquel IR or Seroquel XR (collectively, the "Seroquel Franchise"). Consequently, Defendants anticipated that a significant portion of Seroquel Franchise revenue would be derived from public sector payors, such as Texas Medicaid.[26] Understanding the need to obtain significant government buy-in to achieve their financial goals for the Seroquel Franchise, Defendants set their sights on Texas Medicaid, declaring it "low hanging fruit" and "an ABSOLUTE MUST WIN" that would fuel brand growth.

F. Texas Medicaid

1. Overview

40. The state and federal governments fund health care for the poor and mentally ill through public health assistance programs. Government assistance programs incur the vast majority of the prescription drug costs associated with the treatment of mental illness in the United States. The Medical Assistance Program in Texas, commonly referred to as Texas Medicaid, was created to provide medical assistance for low-income individuals and families in Texas. Since January 2007, over 70% of Texas Medicaid enrollees have been 18 years of age or younger.[27]

41. The Texas Medicaid program, which includes Texas Medicaid decision makers as well as Texas Medicaid providers, is a system that provides medical products and services to qualified recipients. Texas Medicaid reimburses participating providers for the approved

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[26] Documents specific to Defendants' conduct in Texas describe Texas Medicaid as being their "number one payer" in the state.

[27] *See* http://www.hhsc.state.tx.us/research/MedicaidEnrollment/ME-Monthly.asp.

pharmaceuticals they provide to Medicaid recipients. The program is funded jointly by the State of Texas and the federal government. The Texas Health and Human Services Commission ("HHSC") administers the Texas Medicaid program and has authority to promulgate rules and other methods of administration governing the program.

2. Texas Medicaid Tools for Managing Appropriate and Cost-Effective Pharmaceutical Therapy

42. The Vendor Drug Program ("VDP") within HHSC was established to oversee the outpatient prescription drug portion of the Texas Medicaid program, and was in operation at all times relevant to this case.

43. Providers can obtain reimbursement through VDP for pharmaceutical products approved for use and reimbursement under this program, and which are listed on the VDP formulary.[28] Texas Medicaid, like all state Medicaid programs, is only authorized by federal law to reimburse for "covered outpatient drugs" and is not authorized to reimburse for drugs that are used for an indication which is not "medically accepted." An indication or use is not "medically accepted" unless it is approved by the FDA or supported by at least one of three compendia enumerated under the Federal Medicaid Act. *See* 42 U.S.C. § 1396r-8(k)(3), (6); 42 U.S.C. § 1396r-8(g)(1)(B)(i).

44. To have its particular pharmaceutical products listed on the VDP formulary, a drug company or manufacturer must file an application with VDP.[29] Included in the application is a detailed 16-point questionnaire that, pursuant to state law, must be completed and filed. Texas Medicaid requires information provided to it by pharmaceutical manufacturers as part of

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[28] 1 TEX. ADMIN. CODE § 354.1831 (a). The VDP formulary is also referred to as the Texas Drug Code Index or "TDCI."

[29] 1 TEX. ADMIN. CODE § 354.1921 (b).

the VDP application process to be complete, truthful, and up-to-date.[30]

45. VDP applications require drug manufacturers to report, for each drug submitted, the recommended daily dosages, formulation of the drug, FDA approval letters, and copies of the package inserts and materials for physicians. The VDP application also requires manufacturers to certify that all the information provided with their application is correct and that their drug is not in violation of either state or federal law. The application further requires manufacturers, on a going-forward basis, to submit notification of any changes pertaining to their product's status within fifteen (15) days of such changes occurring.

46. In approving VDP applications, HHSC expressly provides that manufacturers are responsible for submitting notification of changes pertaining to the 16 points specified in the application no later than the date such revisions are scheduled to occur. Accordingly, manufacturers owe a continuing duty to Texas Medicaid to supplement information provided with their VDP application after its initial submission to the VDP. Moreover, a new VDP application must be submitted each time a drug first becomes available in a new formulation or in different dosages.

47. Pharmaceutical manufacturers' interactions with Texas Medicaid, and Texas Medicaid's review of drugs placed on its formulary, do not stop with submission of the initial VDP application. Texas Medicaid has an on-going obligation to manage its drug formulary through Drug Utilization Review ("DUR") in accordance with the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90"). Pursuant to that obligation, Texas Medicaid created the DUR program to promote optimal and cost-effective pharmaceutical therapy in the Texas

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30 *Id. See also* 1 TEX. ADMIN. CODE § 354.1923 (b).

Medicaid VDP.[31]

48. Specifically, the DUR program exists to ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical outcomes. The program is designed to educate pharmacists and physicians to identify and reduce the frequency of patterns of fraud, abuse, overuse, or inappropriate or medically unnecessary care associated with specific drugs or groups of drugs.

49. The DUR Board has a number of tools available to it to achieve these goals, including prior authorization, educational letters expressing therapeutic concerns to Texas Medicaid providers, DUR alerts, and clinical edits. If necessary, the DUR Board initiates recommendations that certain drugs be made subject to prior authorization or to restrictions concerning the types of patients (*e.g.*, children, elderly persons, etc.) or the types of conditions for which Medicaid reimbursement is obtainable.

50. As part of this program, the DUR Board monitors and analyzes provider-level activity. Drug manufacturers, including Defendants, provide the DUR program with information concerning their drugs. The DUR program expects – and Texas law requires – all such provided information to be complete and accurate.

51. By way of example, due in part to the great expense and serious potential side-effects associated with atypical antipsychotics, the DUR Board has mailed out a number of retrospective intervention letters targeting unproven atypical use. One such retrospective intervention from June 2007 was proposed as a result of observed increases in atypical antipsychotic utilization,[32] including off-label uses. Concerns about this increased atypical use

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31 1 TEX. ADMIN. CODE § 351.3 (3).

32 At this time in 2007 there were six available atypicals: clozapine, Risperdal, Seroquel IR, Zyprexa, Abilify, and Geodon.

led the DUR Board to approve the proposed intervention, resulting in intervention materials being mailed to a target group of over 3,800 Texas physicians. Additionally, where the DUR Board has specific evidence of improper conduct, even more stringent initiatives can be taken. For instance, in April 2008, the DUR Board implemented a clinical edit targeting the widespread usage of low dose Seroquel IR as a sleep aid, stemming, in part, from AstraZeneca's illegal promotion of the 50mg tablet, which was below the lowest dose for any FDA-approved condition. However, the DUR Board's ability to take such restrictive action is limited by its knowledge of the unlawful conduct. Thus, the DUR Board cannot effectively address issues of improper utilization where the illicit promotional scheme is concealed by the drug company.

52. In February 2004, Texas Medicaid implemented another means through which Texas Medicaid could manage its expenditures for pharmaceuticals – the Texas Medicaid Preferred Drug List (the "PDL").[33] In making recommendations for the PDL, the Texas Medicaid Pharmaceutical and Therapeutics Committee (the "P&T Committee") considers the clinical efficacy, safety, and cost-effectiveness of each drug reviewed.[34] As part of this PDL process, the P&T Committee receives information from drug manufacturers, including Defendants, concerning their drugs. The P&T Committee expects – and Texas law requires – all such information to be complete and accurate. HHSC then decides which drugs are placed on the PDL based on P&T Committee recommendations, the cost of competing drugs to the state, clinical considerations, written information offered by manufacturers about their products, and the existence of a supplemental rebate agreement and/or other program benefits. Drugs that are reviewed but not selected for the PDL require prior authorization. Defendants sought and achieved the placement of both Seroquel IR and Seroquel XR on the PDL without prior

33 1 TEX. ADMIN. CODE § 354.1924.
34 1 TEX. ADMIN. CODE § 354.1928.

authorization, including by making presentations to the P&T committee and submitting written information to the State and/or State contractors concerning Seroquel IR and Seroquel XR. As with the DUR Board, the P&T Committee cannot effectively make recommendations to manage the preferred drug list where material information has been misrepresented and/or concealed by a drug company.

3. **The Texas Medicaid Program**

53. As discussed above, Texas Medicaid includes not just the Medicaid decision makers such as the VDP, DUR, and P&T committee members, but also Medicaid providers such as pharmacies and physicians, which enter into agreements with Texas Medicaid in order to be covered providers. Together, Texas Medicaid decision makers and providers constitute the Texas Medicaid program. The Texas Medicaid Fraud Prevention Act seeks to protect against fraud at all levels of the Texas Medicaid program. *See* TEX. HUM. RES. CODE § 36.001 *et seq.*

VI. APPLICABLE TEXAS STATUTORY AND COMMON LAW

54. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 53 of this Petition.

55. A person commits an unlawful act as defined under the Texas Medicaid Fraud Prevention Act by, among other things:

A. Knowingly making or causing to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE § 36.002 (1).

B. Knowingly concealing or failing to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE § 36.002 (2).

C. Knowingly making, causing to be made, inducing, or seeking to induce the making of a false statement or misrepresentation of material fact

concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program. TEX. HUM. RES. CODE § 36.002 (4) (B).

D. Knowingly paying, charging, soliciting, accepting, or receiving, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program. TEX. HUM. RES. CODE § 36.002 (5).

E. Knowingly engaging in conduct that constitutes a violation under TEX. HUM. RES. CODE § 32.039(b). TEX. HUM. RES. CODE § 36.002 (13).

Hereinafter, references to conduct as constituting "statutory fraud" mean that the conduct being described was done by Defendants at times when one or more of the statutory provisions set forth in this Paragraph 55 applied, and was done in ways and through means that satisfy all the required elements of at least one applicable statutory provision.

56. Under Texas common law a person commits fraud by:

A. Making representations of material facts that are false, with knowledge that such representations are false, or by making misrepresentations recklessly, as a positive assertion, and without knowledge of their truth, with the intent that the victim act upon such representations; or by

B. Failing to disclose material facts within that person's knowledge, which he had a duty to disclose, knowing that the victim is not aware of the concealed facts and does not have an equal opportunity to discover the truth, with the intent to induce the victim to take action by failing to disclose those facts.

Hereinafter, references to "common law fraud" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in Subparagraph A or B of this Paragraph 56.

57. Under Texas law it is illegal for persons to actively encourage, induce, or assist a fiduciary to breach his fiduciary duties. Persons commit this unlawful act by knowingly participating in a fiduciary's breach of his fiduciary duties owed to the victim, if such

wrongdoers knew, or reasonably should have known, that their conduct would cause the fiduciary to breach the fiduciary duties owed to the victim. Hereinafter, references to "aiding or abetting breach of fiduciary duty" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in this Paragraph 57.

58. Under Texas law, a person commits the tort of negligent misrepresentation if, in the course of his business or transactions in which he had pecuniary interests, he supplies information that is false, for the guidance of others, and he fails to exercise reasonable care or competence in obtaining or communicating the information. Hereinafter, references to "negligent misrepresentation" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in this Paragraph 58.

59. Under Texas law, if a victim, unaware of a wrongdoer's unlawful acts, pays money that would otherwise not have been paid, such that the wrongdoer holds money that in equity and good conscience belongs to the victim, the retention of those funds by the wrongdoer would be inequitable and unjust. Hereinafter, references to "monies had and received" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in this Paragraph 59.

60. Under Texas law, a victim can recover under promissory estoppel if a wrongdoer made a promise to the victim, the victim reasonably and substantially relied on the promise to its detriment, the wrongdoer could have foreseen the victim's reliance on the promise, and injustice can be avoided only by enforcing the wrongdoer's promise. Hereinafter, references to "promissory estoppel" mean that the conduct being described was done by Defendants in ways and through means that satisfy all the required elements set forth in this Paragraph 60.

VII. DEFENDANTS' UNLAWFUL ACTS

61. In 2006 Defendants were made aware of a joint federal and state investigation ("2006 Investigation") into the promotion of Seroquel IR, including allegations that Defendants unlawfully promoted Seroquel IR for use in depression and within the child and adolescent population.[35] In an attempt to quietly resolve these allegations, Defendants began negotiating towards a settlement agreement.

62. Settlement negotiations continued into 2010, at which time Defendants agreed to pay $520 million for dismissal of the claims associated with the 2006 Investigation.[36] Additionally, Defendants entered into a Corporate Integrity Agreement ("CIA") with the U.S. Department of Health and Human Services' Office of the Inspector General ("OIG"), which imposed a number of compliance-related obligations upon the company, including internal company oversight and various reporting requirements. This settlement covered Defendants' promotional conduct relating to Seroquel IR from January 2001 through December 2006.

63. Far from being a good corporate citizen, Defendants did not alter their unlawful promotional tactics even after learning about the allegations in the 2006 Investigation. In fact, one of the few actions Defendants took in advance of the impending 2010 settlement was to eliminate free-text call notes, a major source of evidence for government regulators, which had the effect of further concealing their ongoing unlawful promotional scheme.

64. In 2007 and beyond, Defendants continued promoting Seroquel IR in a manner that caused the drug to be misbranded, while concurrently negotiating for a settlement. This unlawful scheme later transitioned to Seroquel XR in 2009, when Defendants became concerned

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35 Such off-label promotion may serve as evidence of a new intended use for the drug, resulting in the drug being unlawfully misbranded.

36 *See* http://www.justice.gov/opa/pr/2010/April/10-civ-487.html.

regarding the limited remaining duration of the Seroquel IR patent.

A. Defendants Promoted the Seroquel Franchise for Use in the Child and Adolescent Population, Thereby Misbranding the Products

65. At no point during the time that Defendants promoted Seroquel IR[37] did Seroquel IR have an indication for use in the child and adolescent population. Similarly, at no point prior to April 2013 did Seroquel XR have an indication for use in the child and adolescent population. Yet, at all times prior to April 2013, Defendants required the CNS sales force to promote the Seroquel Franchise to doctors named on a company-provided list of physicians – the "call plan" – that included a significant number of child and adolescent psychiatrists.

66. Furthermore, at all relevant times Defendants incentivized misleading off-label promotion through the "Field Sales Incentive Plan" ("FSIP") by rewarding sales representatives equally for off-label and on-label prescriptions. Sales representatives were evaluated based on, and provided with monetary incentives for, the total volume of Seroquel Franchise prescriptions generated in their territory, regardless of why or to whom the doctor wrote the prescription.

67. Defendants understood at least by 2006, when the first Seroquel investigation was partially unsealed, that it was unlawful to promote Seroquel for use in the child and adolescent population, absent having an appropriate pediatric indication. Yet, in response to learning of – and beginning settlement negotiations for – the 2006 Investigation, Defendants wholly failed to alter the systematic manner in which they targeted child and adolescent psychiatrists. Instead, Defendants merely concealed their overt pediatric promotional efforts while continuing to require the CNS sales force to make hundreds of calls to child and adolescent psychiatrists on a

[37] Defendants switched all promotional efforts from Seroquel IR to Seroquel XR in February 2009 in anticipation of Seroquel IR's patent protection expiring. Seroquel IR later gained a limited pediatric indication in December 2009, ten months after all promotion for the drug had ceased.

weekly basis.

68. Moreover, Defendants had full knowledge of what actions could have been taken to curb off-label pediatric promotion. Shortly after becoming aware of the 2006 Investigation, one e-mail between Defendants' Targeting and Performance ("T&P") team and national sales leadership noted that Defendants' legal team may ask T&P to remove non-indicated physicians (*i.e.*, child and adolescent psychiatrists) from being counted towards sales representative incentive compensation, in order to avoid encouraging misleading and off-label promotion. Despite being aware of this potential solution, no such wholesale off-label script exclusion was implemented by Defendants, and Seroquel IR's pediatric market share continued to grow.

69. Defendants additionally understood exactly what was at stake, in terms of potential sales dollars, if they were to end pediatric promotional efforts. In a 2008 e-mail, Defendants' CNS National Sales Director asked the T&P team to perform an analysis showing what the impact in sales would be if all child and adolescent psychiatrists were removed from CNS call plans. The T&P team responded that Defendants would stand to lose $113.8 million annually if this change occurred, noting that "the impact could be significant" and that this was "a substantial amount of business to have no promotional efforts." Following this exchange, no such change was made to eliminate pediatric promotion of the Seroquel Franchise.

70. Simply put, Defendants prioritized increasing sales figures over complying with federal and state regulations, leading the national sales leadership to reject solutions to one of the main issues that gave rise to the 2006 Investigation. Further, these two e-mail exchanges evidence Defendants' high-level intent to expand the Seroquel Franchise within the child and adolescent population at a time when neither drug had an appropriate indication, while Defendants continued to negotiate for a settlement in the 2006 Investigation.

71. In furtherance of this objective, Defendants' Seroquel Franchise Brand Team closely tracked Seroquel IR's market share in the pediatric population. Defendants' internal documents show that Seroquel IR's growth in this off-label population trended upward until around mid-2008, when Seroquel's main competitor, Abilify, obtained an FDA indication for use in the child and adolescent population.

72. As could be expected, the effect of Defendants' high-level intent to grow the Seroquel Franchise in the pediatric population cascaded down to the regional and district levels, creating a sales environment in which off-label promotion of the Seroquel Franchise for use in children was encouraged and rewarded.

73. Both nationally and in Texas, Defendants' CNS call plans consisted of around ten to fifteen percent child and adolescent psychiatrists. However, in Texas, these ten to fifteen percent typically accounted for a disproportionately-high amount of total Seroquel Franchise prescription volume within a sales representative's territory. For example, within the San Antonio district, CNS sales representatives noted that child and adolescent psychiatrists constituted approximately 70% of their total territory volume. Likewise, in the Dallas district, child and adolescent psychiatrists were described as "dominat[ing] and driv[ing] our book of business," with six of ten top accounts being child and adolescent psychiatrists in one territory. For these sales representatives, it would have been impossible to achieve the sales quotas established by Defendants' sales leadership without promoting to their respective territory's high-volume child and adolescent psychiatrists.

74. Defendants additionally utilized the following promotional tactics to improperly expand usage of the Seroquel Franchise in the pediatric population:

- Hiring influential child and adolescent psychiatrists as Key Opinion Leaders ("KOLs") to discuss using the Seroquel Franchise with other child and

adolescent providers during lunch and dinner speaker programs;

- Creating "Abilify Offender" lists, which identified and targeted high-Abilify-prescribing psychiatrists, many of whom were child and adolescent providers, at a time when Abilify had a child and adolescent indication and the Seroquel Franchise did not; and

- Targeting Texas Medicaid providers, many of whom (as a result of the demographics of Texas Medicaid enrollees) served large child and adolescent populations.

75. Defendants misleadingly promoted the Seroquel Franchise to child and adolescent psychiatrists to increase the utilization of the Seroquel products for children – which was in fact achieved. By promoting the Seroquel Franchise in this manner, Defendants knew or reasonably should have known that the drugs would be widely used off-label for children, thus creating a new intended use for Seroquel IR and Seroquel XR. As a result of this misleading promotional scheme, Defendants caused the Seroquel Franchise to be misbranded in violation of federal and state law.

C. Defendants Misleadingly Promoted Seroquel IR for Use in Depression, Thereby Misbranding the Product

76. At least as early as 2005, Defendants were aware that Seroquel IR was gaining market share in off-label conditions, including depression, while market share for schizophrenia was declining. In order to continue growing Seroquel IR in the off-label depression market, Defendants developed a high-level strategy within their 2006 Product Strategic Plan to promote Seroquel IR by misleadingly claiming it was effective for use in "a broad range of depressive symptoms such as anxiety." This type of broad symptom-based promotion fails to distinguish between the various mood disorders, including MDD, and misleadingly suggests that Seroquel IR is effective and/or indicated for the treatment of MDD, as MDD and bipolar depression share the same core set of depressive symptoms.

77. After obtaining Seroquel IR's bipolar depression indication in October 2006, Defendants held a company-wide Business Emphasis Meeting ("BEM") to disseminate the new misleading Seroquel IR promotional strategy to the entire CNS sales force and to train the sales force to use these messages through a series of hands-on workshops. Maintaining the high-level plan established the prior year, Defendants included among the strategic messages that "Seroquel helps reduce their depression, irritability, racing thoughts and anxiety symptoms." Defendants further focused on this misleading, broad symptom-based sales approach by generally referring to Seroquel IR's efficacy in depressive symptoms, and by specifically referencing Seroquel IR's efficacy in each individual MADRS symptom.[38]

78. Following this BEM and into 2007, Defendants' CNS sales teams throughout Texas implemented Defendants' plan to misleadingly position Seroquel IR broadly for use in depressive symptoms. E-mails show CNS District Sales Managers ("DSMs") sending reminder messages to their sales force emphasizing the broad symptom-based sales approach as dictated by Defendants' national sales strategy. Understanding the clear direction from sales leadership, sales representatives systematically delivered the misleading, broad symptom-based messages to Texas healthcare providers, including providers participating in the Texas Medicaid program and providers appointed as Texas Medicaid decision makers. Numerous call notes and Field Coaching Forms (FCFs) reflect the implementation of this misleading symptom-based sales approach at the local level within Texas.

79. Sales representatives were periodically required by their DSMs to formulate a "territory plan," which involved taking the company-driven messaging and adapting it for local

[38] "MADRS" refers to the Montgomery–Åsberg Depression Rating Scale ("MADRS"), which measures the severity of depressive episodes in patients with mood disorders. Measured components within the MADRS include apparent and reported sadness, inner tension, and reduced sleep, among others.

use. One example of a territory plan is seen in a Houston district in 2008, where the sales representatives developed a plan focusing "on educating the physicians on the rise in depressive symptoms during this specific time of year. We will use the [MADRS] and point out specific symptoms that [patients] may present with because of the holidays."

80. By all accounts, Defendants' effort to broadly and misleadingly promote their potent antipsychotic medication for use in depression was a success. Defendants understood that depression was an off-label condition for Seroquel IR, yet Defendants closely tracked Seroquel IR's market share and performance within the MDD population. When growth in the MDD population appeared to slow, such as in mid-2008 when competitor antipsychotic Abilify obtained an adjunctive-MDD indication, Defendants took notice. Defendants' documents noted that Abilify was ramping up on-label MDD promotion "into the depression space where Seroquel should be the clear leader." Nonetheless, by 2008, Seroquel IR's off-label market share in MDD was greater than its on-label market share in bipolar depression, which (by virtue of the physicians targeted in Defendants' call plans) would have included a significant number of prescriptions for depressed and anxious pediatric patients.

81. Internally, Defendants recognized the success of this promotional campaign and expanded their goals to "[e]stablish Seroquel as a future 1st choice atypical for patients with MDD or GAD." Similarly, in a separate e-mail, Sales Team leadership noted that "[t]he launch success for future indications for SEROQUEL, like MDD and GAD, depends on building a solid foundation [today] in depressive symptoms."[39] Establishing Seroquel as a "future 1st choice" or laying the foundation for an off-label indication necessarily requires present off-label promotion. To further their objectives, Defendants sought to utilize KOLs, publications, advisory boards,

[39] "Today" appears in brackets in Defendants' document, as a suggested addition to the document.

and other promotional tactics.

82. Defendants' planning and promotion of Seroquel IR for use in depressive symptoms was carefully calculated to reach beyond patients diagnosed with bipolar disorder and into the off-label unipolar depressed (MDD) population. By planning to promote, and then promoting, Seroquel IR in this false and/or misleading manner, Defendants created a new intended use and/or disseminated false and/or misleading advertisements for Seroquel IR, causing the drug to be misbranded in violation of federal and state law.

C. Defendants Misleadingly Promoted Seroquel XR for Broad Use in Depression and as an "Antidepressant," Thereby Misbranding the Product

83. As part of Defendants' plan to expand the use of Seroquel beyond the most severe and debilitating psychiatric disorders, and into MDD and GAD, Defendants performed preliminary market research in the MDD and GAD populations to determine how best to approach these conditions. Defendants discovered, however, that the physicians most frequently involved in diagnosing and treating these more-common conditions – Primary Care Physicians ("PCPs") – were reluctant to prescribe atypical antipsychotics such as Seroquel for broad use in depression, for fear of the litany of side effects associated with this class of potent medications. Defendants' market research also revealed that PCPs instead preferred mood stabilizers and antidepressants, which had different side effect profiles. As described by Defendants' "XR Immersion Day" presentation in 2008, atypicals (including Seroquel) were perceived as "big guns with big baggage" by PCPs; likewise, the term "atypical antipsychotic" was itself viewed as being "conceptually confining" by the "Seroquel Science Strategy Team Update" in 2008.

84. Utilizing this information, Defendants saw an opportunity to differentiate Seroquel XR, both from atypicals generally and from Seroquel IR specifically: rather than launching it as another atypical antipsychotic, Defendants planned to launch Seroquel XR as an

antidepressant. By misleadingly promoting Seroquel XR as an antidepressant, Defendants would effectively conceal Seroquel XR's class-wide side effects typically associated with atypicals, and simultaneously reach the broader depression market, while creating the illusion that it was an entirely new medication for different purposes, and not just an extended-release version of Seroquel IR. Indeed, Defendants' "CNS Long Term Training Plan" from 2008 describes the deception of "[c]hanging the physician's mindset to view Seroquel as an efficacious antidepressant rather than an atypical antipsychotic" as being one of the "Challenges" facing the company in 2009.

85. To further this scheme, Defendants drastically altered the call plans of the CNS sales force in mid-2008 by adding a significant number of general practice PCPs, who Defendants knew would be seeing a large number of MDD and GAD patients. Up to that point, the CNS sales force had primarily called on psychiatric specialists.

86. In late December 2008, FDA informed Defendants that Seroquel XR **would not** be receiving an MDD indication as Defendants had anticipated, due to FDA having insufficient information regarding Seroquel XR's long-term risks in this more-common, non-psychotic, population. Additionally, FDA noted, there already existed a number of available effective MDD treatments, including SSRIs[40] and SNRIs[41] (among others), commonly referred to as "antidepressants," which did not have the long-term safety risks that Seroquel XR has.

87. Undeterred by FDA's denial of the MDD indication, Defendants nominally refocused the previously planned Seroquel XR MDD launch to the existing bipolar depression indication, in what the Brand Team referred to as the "new direction." In actuality, Defendants' "new direction" consisted of maintaining the same sales goals, same method of accomplishing

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40 Selective serotonin reuptake inhibitors.
41 Serotonin–norepinephrine reuptake inhibitors.

the sales goals (via misleadingly rebranding Seroquel XR as an antidepressant), and same MDD disease-state training as had been established for the MDD indication launch. For instance, in anticipation of the potential MDD indication, which would have greatly expanded the on-label patient base for Seroquel XR, Defendants planned to increase the sales quotas for sales representatives. This planned increase was implemented even after the MDD indication was denied by FDA, forcing sales representatives to find new ways to achieve sales of Seroquel XR. Defendants also maintained the strategy of targeting patients that were diagnosed with MDD and unsatisfied with their current treatment – an off-label population – and misleadingly promoting Seroquel XR for use in individual depressive symptoms. This resulted in numerous false and/or misleading promotional messages that Defendants intended to use to obtain market share in the off-label MDD population, including, but not limited to:

- Positioning Seroquel XR as an effective monotherapy antidepressant;
- Focusing on a patient type that is diagnosed with MDD, being treated with an SSRI or SNRI, or another atypical, but still experiencing depressive symptoms;
- Stating that Seroquel XR is effective in treating particular depressive symptoms such as sadness, loss of interest, and feelings of worthlessness; and
- Selling against Abilify, which had an adjunctive-MDD indication at the time of Seroquel XR's launch.

88. Consistent with Defendants' national brand strategy, Defendants' sales representatives in both the CNS and MCL[42] sales force teams were trained to deliver, and consistently delivered, these false and/or misleading promotional messages to Texas healthcare providers, including providers participating in the Texas Medicaid program and providers

[42] MCL (Medical Care Left) was another branch of Defendants' sales force, which promoted Seroquel IR and Seroquel XR, among other AstraZeneca drugs, primarily to family doctors (PCPs) and internal medicine practitioners.

appointed as Texas Medicaid decision makers. Ultimately, Defendants' misleading promotion of Seroquel XR as an antidepressant was successful in expanding the market of Seroquel XR for broad use in depression, which as a result of the physicians targeted in Defendants' call plans, would have included a significant number of depressed pediatric patients.

89. Not all sales representatives were aligned with Defendants' new Seroquel XR launch messaging. In the spring of 2009, a Dallas-based sales representative made an audio recording of a district teleconference wherein the DSM sought to share best practices from the field, and to reinforce Defendants' brand messaging. Sales representatives on this recorded teleconference discussed recent interactions with the CNS Regional Sales Director ("RSD") covering the South Central Region, which included Texas and several other states. Among the messages relayed by the RSD to the sales representatives were misleading messages intended to increase the use of Seroquel XR for depression and as an antidepressant, which was in-line with the Seroquel XR national brand strategy.

90. This Dallas-based sales representative reported her DSM and RSD to Defendants' compliance department for off-label promotion. As part of this report, the sales representative submitted her audio recordings from the district teleconference. Defendants, despite having concrete evidence of misleading off-label promotion occurring in the South Central Region, took no action for several months.

91. In October 2009, Defendants circulated an internal memo to its entire Seroquel sales force stating that the sales force must ensure "proper communication" of Seroquel XR's indications. Provided in this memo were examples of improper Seroquel XR messages, including messages relating to promoting Seroquel XR as an antidepressant, promoting Seroquel XR for use in patients diagnosed with MDD, and promoting Seroquel XR for the individual

symptoms of depression. Defendants additionally terminated the RSD implicated in the audio recordings and demoted several DSMs around Texas. Yet, Defendants' corrective efforts were merely superficial, as Defendants did not address that the National Brand Team was responsible for the improper and misleading messaging. Numerous e-mails and documents show that the Brand Team was not only aware of the improper messaging being disseminated at the regional level, but was the very source of said improper messaging. In spite of this internal memo, Defendants continued to misleadingly refer to Seroquel XR as an "antidepressant" into 2010 and beyond.

92. Defendants' planning and promotion of Seroquel XR for use as an "antidepressant" and in the depressed population demonstrates Defendants' intent to reach beyond bipolar depressed patients and into the off-label MDD population. By planning to promote, and then promoting, Seroquel XR in this false and/or misleading manner, Defendants created a new intended use and/or disseminated false and/or misleading advertisements for Seroquel XR, causing the drug to be misbranded in violation of federal and state law.

D. Defendants Provided Illegal Kickbacks to, and Unduly Influenced, Texas State Mental Health Officials and Decision Makers, in Violation of State Law

93. In an effort to increase utilization of the Seroquel Franchise within Texas, Defendants sought to influence decision-making within the Texas medical community generally, and the Texas state hospital system[43] specifically, by providing illegal payments to at least two state hospital employees.[44]

94. Defendants' e-mails and documents show Defendants knew that state hospital inpatients commonly maintain their medications upon discharge, at which time reimbursement

[43] State hospitals in Texas are administered by the Department of State Health Services ("DSHS") and are funded, in part, by Medicaid, on a capitated basis. Texas state hospitals primarily serve patients on an inpatient basis.

[44] State hospital employees are public servants and employees of Texas.

for many of those medications would be through Texas Medicaid. Accordingly, Defendants targeted Texas state hospitals, in part, for the purpose of increasing Texas Medicaid utilization.

95. In furtherance of this objective, from at least 2008 to present, Defendants paid over $465,000 to two state mental health officials with the power to influence formulary decisions within the state hospital system.[45] Defendants ostensibly made these payments for promotional speaking engagements; however, Defendants' internal e-mails and documents reveal that Defendants' motivation for paying these two state mental health officials was actually: 1) to use them to influence the DSHS Executive Formulary Committee ("EFC"); and 2) to induce them to recommend use of the Seroquel Franchise to other Texas healthcare providers, particularly, to other state hospital, MHMR, and Medicaid providers, based on their positions as state officials.[46]

96. For instance, in an October 2008 e-mail, one of Defendants' Institutional Sales Specialists (ISS) discusses Defendants' efforts to use state mental health officials to serve as Defendants' proxies in recommending that Seroquel XR be added to the DSHS formulary. During this discussion, the ISS explicitly describes Defendants' motive behind paying the state mental health officials: "While I have attached the Executive Formulary Committee Members names and attendance over the last year, let us not forget the non-committee members who can truly help us. [The AstraZeneca-paid state mental health officials] **are very influential** in the DSHS system." (Emphasis added).

97. This conduct continued into 2009, when Defendants were able to obtain a formal

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[45] State hospitals use a drug formulary as established by the DSHS Executive Formulary Committee – separate from VDP.

[46] In addition to violating the provisions of the TMFPA related to kickbacks, such payments to public servants *because* they are public servants violate the Texas Penal Code section 36.09 prohibition on the offering and conferring of such payments.

recommendation from one of the AstraZeneca-paid state mental health officials to request addition of Seroquel XR to the DSHS formulary. In preparation for the EFC's upcoming vote relating to the addition of Seroquel XR, in May 2009, one of Defendants' RSDs scheduled a Texas state hospital formulary strategy conference, wherein the two paid state mental health officials were referred to as being "key influencers" and "champions" that would be used to leverage their relationships with EFC voting members. In June 2009, the RSD followed up with a "Texas State Formulary Strategy Update," wherein an ISS was paired with a state mental health official for the purpose of targeting and influencing EFC voting members, on Defendants' behalf. Such conduct additionally exemplifies how Defendants' influence over the paid state mental health officials resulted in those state-employed doctors placing Defendants' interests ahead of state interests.

98. As late as December 2010, Defendants' internal documents refer to the two AstraZeneca-paid state mental health officials as being Defendants' "strongest advocates." As well, Defendants' own employees took credit for achieving utilization of XR at one of the state hospitals, despite XR not being on the state formulary, by building advocacy with the hospital's clinical director – one of the AstraZeneca-paid state mental health officials.

99. Beyond attempting to affect formulary decisions in the state hospital system, Defendants also induced the state mental health officials to recommend that other healthcare providers use the Seroquel Franchise, including providers participating in the Medicaid program. Defendants' documents in 2008 and 2009 show that Defendants used the AstraZeneca-paid state mental health officials to target healthcare providers that were perceived as being infrequent prescribers of the Seroquel Franchise. Indeed, Defendants explicitly planned in 2009 to "grow XR utilization" by "leverage[ing]" the AstraZeneca-paid state mental health officials within state

hospitals and MHMR systems. Following such a visit with the AstraZeneca-paid state mental health officials, Defendants' sales representatives would often note an associated increase in Seroquel Franchise utilization. The substance of the presentations provided by these AstraZeneca-paid state mental health officials is revealed in Defendants' "Seroquel XR: 2010 Speaker Training Update" as being "promotional content" developed by Defendants and provided in slideshow format to the state mental health officials.

100. By paying large sums of money to state mental health officials for the purpose of utilizing their influence over the EFC, local formularies, and Texas healthcare providers, Defendants violated the state anti-kickback statute and thereby violated the TMFPA. Additionally, the state mental health officials referenced in this Section were persons who owed a fiduciary duty to the State of Texas, and Defendants' conduct in this Section constitutes aiding or abetting breach of fiduciary duty under state common law principles.

E. Defendants Promoted the Seroquel Franchise Using Various False and/or Misleading Messages, Thereby Misbranding the Products

1. Defendants Misrepresented Seroquel IR's Side Effect Profile, Thereby Misbranding the Product

101. One of the most common side effects associated with use of Seroquel IR is that of somnolence or sedation. Defendants and Defendants' sales representatives used various false and/or misleading promotional messages in an attempt to minimize concerns regarding this side effect, including, but not limited to:

- Claiming that sleep is beneficial and helps to re-establish mood-stabilization;
- Claiming that somnolence is part of the underlying disease (*i.e.*, bipolar disorder), and thus it is the underlying disease, not Seroquel IR, causing the somnolence;
- Claiming that to the extent Seroquel IR causes somnolence or sedation, it is only transient in nature and will dissipate; and

- Claiming that Seroquel IR helps to restore "sleep architecture."

102. Defendants' sales representatives in both the CNS and MCL sales teams delivered these misleading promotional messages on numerous occasions to Texas healthcare providers, including providers participating in the Texas Medicaid program.

103. Any such attempts by Defendants to suggest that Seroquel IR's sedating qualities are actually caused by the underlying disease, are transient in nature, or are a benefit rather than a side effect, are false and/or misleading, and contrary to the FDA-approved labeling.

104. Furthermore, Defendants created new intended uses and/or disseminated false and/or misleading advertisements for Seroquel IR by promoting it for the purposes of causing sedation to stabilize mood and restoring "sleep architecture," causing Seroquel IR to be misbranded in violation of federal and state law.

2. Defendants Misrepresented Seroquel XR's Side Effect Profile, Thereby Misbranding the Product

105. As Seroquel XR consists of the same active ingredient as Seroquel IR (quetiapine fumarate), somnolence is similarly one of XR's most frequent side effects. In an attempt to differentiate Seroquel XR from Seroquel IR at a time when the two drugs had identical indications, Defendants and Defendants' sales representatives disseminated false and/or misleading promotional messaging, including, but not limited to:

- Claiming that Seroquel XR had less sedation than Seroquel IR, including through the use of a "PK chart" and "Study 33";
- Claiming that proper dosing of Seroquel XR in the evening would eliminate issues of daytime sedation;
- Claiming that Seroquel XR has a "clean side effect profile"; and
- Claiming that Seroquel XR has fewer side effects than Seroquel IR.

106. Defendants' sales representatives in both the CNS and MCL sales teams delivered these promotional messages on numerous occasions to Texas healthcare providers, including providers participating in the Texas Medicaid program.

107. Any such attempts by Defendants to suggest that Seroquel XR's side effects, including its sedating qualities, are less than those caused by Seroquel IR (or are altogether non-existent), are false and/or misleading, and contrary to the FDA-approved labeling.

108. Furthermore, Defendants created a new intended use and/or disseminated false and/or misleading advertisements for Seroquel XR by promoting it for the purpose of being a low-somnolence treatment option, causing Seroquel XR to be misbranded in violation of federal and state law.

3. Defendants Misrepresented Seroquel XR's Efficacy in Adjunctively Treating Major Depressive Disorder, Thereby Misbranding the Product

109. In December 2009, Defendants eventually gained a limited FDA approval for Seroquel XR for use as an adjunctive treatment to an antidepressant. Defendants launched Seroquel XR's adjunctive-MDD campaign in February 2010, transitioning all Seroquel XR promotion from bipolar depression to the new indication.

110. By 2010 there were a number of options for the treatment of MDD, including both older, generic drugs, such as tricyclic antidepressants, and newer drugs used adjunctively, such as Abilify.[47] In order to have a successful launch into this already-crowded market, Defendants recognized the need to differentiate their expensive drug from the established, often safer, therapeutic options. Defendants found the market's "unmet need" – the key to achieving

[47] Other pharmacological options for treating MDD included MAOIs, SSRIs, SNRIs, and atypical antidepressants.

success in this market – to exist in the concept of "remission."[48]

111. Within their 2010 Product Strategic Plan, Defendants planned to position Seroquel XR based on its efficacy in helping patients with MDD better achieve "remission." Following this high-level plan, Defendants' Brand Team developed a "remission" strategy statement to convey the brand positioning to the sales force. During Defendants' development of this "remission" strategy statement, the Senior Director of Clinical Development expressed concerns regarding the proposed language. In a January 2010 e-mail to the Brand Team, he wrote:

> However, I'm not thrilled about the phrase "proven to improve remission." In our promotional materials, the term "proven" is invariably followed by the FDA indication, e.g., proven effective in schizophrenia, bipolar depression, etc. With respect to studies 6 and 7, Seroquel XR was proven effective in MDD as adjunctive therapy to antidepressants. Remission was not the primary endpoint in the MDD trials... .

The Brand Team dismissed these concerns without further consultation from the Senior Director of Clinical Development, and Defendants launched Seroquel XR's adjunctive MDD indication using the false and/or misleading "remission" strategy statement.

112. Secondary to remission, Defendants planned to misleadingly promote Seroquel XR for use in the depressed patient experiencing the individual symptoms of sadness and loss of interest.

113. Defendants trained their CNS sales force to deliver the false and/or misleading "remission" and symptom-based patient profile messages, both in the February 2010 national launch meeting, and in later regional-level and district-level meetings. Defendants' sales force, in turn, executed the plan and delivered these false and/or misleading messages on thousands of sales calls to Texas healthcare providers, including to Texas Medicaid providers and decision

[48] As used by Defendants, "remission" in MDD occurs when a patient's total MADRS score is reduced to at most a level of eight after receiving treatment for their depression.

makers. False and/or misleading "remission" messaging delivered to Texas healthcare providers included the following:

- Approximately 50% greater remission rates (MADRS Total Score ≤ 8) Seroquel XR plus an antidepressant vs an antidepressant alone at Week 6;
- In Study 6, Seroquel XR 300 mg/day + AD demonstrated significantly greater remission rates vs placebo + AD at Week 6 (42.5% vs 24.5%, respectively; $P<0.01$);
- In Study 7, Seroquel XR 150 mg/day + AD demonstrated significantly greater remission rates vs placebo + AD at Week 6 (36.1% vs 23.8%, respectively; $P<0.05$); and
- For these [Seroquel XR] studies, remission was defined conservatively as … MADRS Total Score ≤ 8 at Week 6.

False and/or misleading symptom-based patient profile messaging, on the other hand, involved describing a depressed patient who was still experiencing "sadness and loss of interest" despite being treated with an antidepressant. This patient profile was used by Defendants as an example of the type of patient for which a physician should prescribe Seroquel XR.

114. On or about February 26, 2010, Defendants' Neuroscience Field Physician delivered Defendants' false and/or misleading "remission" messages to the Texas Medicaid P&T Committee, on behalf of AstraZeneca, during public testimony. Following this hearing, the P&T committee recommended that Seroquel XR remain on the PDL.

115. Defendants promoted Seroquel XR in this manner until at least July 29, 2010, on which date FDA issued a letter to Defendants, informing Defendants that their promotional labeling relating to Seroquel XR's efficacy in achieving "remission" and in specifically addressing the individual symptoms of sadness and loss of interest as an adjunctive treatment in MDD was false and/or misleading, and caused the drug to be misbranded. According to the FDA letter, the "remission" claims were false and/or misleading because remission was neither a

primary or key secondary measure in the referenced studies; six weeks was not sufficiently long to assess "remission"; and there is no regulatory definition of how to define "remission." For the individual symptom claims, FDA noted that Seroquel XR was only proven to reduce total MADRS scores, and that the clinical trials were not designed to assess Seroquel XR's impact on particular symptoms of MADRS.

116. By misrepresenting Seroquel XR's efficacy through the use of promotional labeling and advertisements that were false and/or misleading, and inconsistent with the FDA-approved label, Defendants caused Seroquel XR to be misbranded in violation of federal and state law.

F. Defendants' Conduct Resulted in Harm to the State of Texas

117. Defendants' fraudulent and sophisticated marketing scheme targeting the Texas Medicaid program, based upon misrepresentations and omissions about Seroquel IR and Seroquel XR, resulted in excessive reimbursements for these drugs by the Texas Medicaid program. Specifically, as a result of Defendants' conduct, the Texas Medicaid program was prevented from making fully informed and appropriate policy decisions, and from utilizing the tools and safeguards available to the Medicaid program, including the VDP, DUR, and PDL processes, to appropriately manage the reimbursement of Seroquel IR and Seroquel XR prescriptions.

VIII. CAUSES OF ACTION

A. Defendants' Violations of the Texas Medicaid Fraud Prevention Act

118. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 117 of this Petition.

1. Defendants' Violations of the TMFPA That Resulted in Harm to The State of Texas, and for Which Plaintiffs Seek Recovery and Civil Penalties

119. Defendants knowingly made or caused to be made false statements and/or misrepresentations of material facts to Texas Medicaid in applying for Seroquel XR's inclusion on the VDP formulary and during the PDL process. Furthermore, Defendants' false statements and/or misrepresentations permitted Defendants to receive benefits under the Medicaid program that were not authorized or that were greater than the benefits authorized, including, but not limited to, inclusion on the VDP formulary and virtually-unfettered reimbursement of Seroquel XR, in violation of the TMFPA. TEX. HUM. RES. CODE § 36.002 (1).

120. Defendants knowingly concealed or failed to disclose events or information from Texas Medicaid in conjunction with the VDP, DUR, and PDL processes. This conduct permitted Defendants to receive benefits under the Medicaid program, including, but not limited to, virtually unfettered reimbursement of Seroquel IR and Seroquel XR, that was not authorized or that was greater than the benefits authorized, in violation of the TMFPA. TEX. HUM. RES. CODE § 36.002 (2).

121. Defendants knowingly or intentionally made, or caused to be made, induced, or sought to induce the making of false statements and/or misrepresentations of material facts concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program in violation of the TMFPA. TEX. HUM. RES. CODE § 36.002 (4) (B).

122. As a result of Defendants' conduct, the Texas Medicaid program was prevented from making fully informed and appropriate policy decisions, and from fully utilizing the tools and safeguards available to the program, including the VDP, DUR, and PDL processes, to appropriately manage the reimbursement of Seroquel IR and Seroquel XR prescriptions.

Defendants' illegal conduct, therefore, resulted in millions of dollars in excessive reimbursements for Seroquel IR and Seroquel XR by the State of Texas. Defendants' conduct additionally resulted in Defendants receiving the benefit of having Seroquel IR and Seroquel XR listed and maintained on the Texas Medicaid formulary during times when the drugs were in violation of federal and state law.

123. Under the TMFPA, each Defendant is liable to the State of Texas for the amount of any payments or the value of any monetary or in-kind benefits provided under the Medicaid program, directly or indirectly, as a result of its unlawful acts; two times the amount of those payments or the value of the benefit; pre-judgment interest on the amount of those payments or the value of the benefit; and a civil penalty for each unlawful act committed, in addition to the fees, expenses, and costs of the State of Texas and the Relators in investigating and obtaining civil remedies in this matter. TEX. HUM. RES. CODE §§ 36.052, 36.007, 36.110 (c).

124. Plaintiffs invoke in the broadest sense all relief possible at law or in equity under TEX. HUM. RES. CODE § 36.052, whether specified in this pleading or not.

125. The amounts sought from each Defendant are in excess of the minimum jurisdictional limits of this Court.

126. The TMFPA is a statute of absolute liability. There are no statutory, equitable, or common law defenses for any violation of its provisions. Further, Texas jurisprudence provides that the defenses of estoppel, laches, and limitations are not available against the State of Texas as a Sovereign. *State v. Durham*, 860 S.W.2d 63, 67 (Tex. 1993).

2. Defendants' Violations of the TMFPA for Which Plaintiffs Seek Civil Penalties

127. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 126 of this Petition.

128. Under the TMFPA, Defendants are liable to the State of Texas for a civil penalty for each unlawful act committed by Defendants without regard to whether that violation resulted in harm. TEX. HUM. RES. CODE § 36.052.

129. Defendants' false and/or misleading messages regarding the safety, efficacy, and appropriate use of Seroquel IR and Seroquel XR were disseminated repeatedly to thousands of Texas Medicaid providers and decision makers. Each time that Defendants knowingly made, caused to be made, induced, or sought to induce the making of such false and/or misleading statements to a Texas Medicaid provider or decision maker concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program, Defendants committed an unlawful act under the TMFPA. *See* TEX. HUM. RES. CODE § 36.002 (4) (B).

130. Defendants' widespread use of a false and/or misleading sales aid in 2010, described in detail in Paragraphs 109 – 116, *supra*, provides just one of numerous examples of such unlawful acts. Defendants' sales aid, which was characterized by the FDA as false and misleading based on its presentation of Seroquel XR remission data in MDD and the use of several individual symptoms of MDD, was utilized by Defendants' sales force during thousands of sales calls to Texas Medicaid providers and decision makers.

131. Defendants also knowingly made, caused to be made, induced, or sought to induce the making of false and/or misleading statements in violation of the TMFPA to Texas Medicaid providers and decision makers through journal publications, promotional materials, advisory boards, continuing medical education ("CME"), company-sponsored speeches, sales calls, and other means.

132. Additionally, Defendants knowingly engaged in conduct that constituted a

violation under TEX. HUM. RES. CODE § 32.039 (b). *See* TEX. HUM. RES. CODE § 36.002 (13). By way of example, from 2008 to present, Defendants have paid over $465,000 to two doctors employed by the State of Texas. Defendants' internal e-mails reveal that these doctors were explicitly valued by Defendants for their influence within the state hospital system, including their ability to influence the placement of Seroquel XR on the DSHS formulary. Defendants also utilized these two state doctors to recommend the use of Seroquel XR to other healthcare providers, including to other state hospital doctors and healthcare providers participating in the Texas Medicaid program.

133. In furtherance of these objectives, Defendants offered or paid, directly or indirectly, overtly or covertly, remuneration, including kickbacks, bribes, or rebates, in cash or in kind to induce a person to purchase, lease, or order, or to arrange for or to recommend the purchase, lease, or order of, any good, facility, service, or item for which payment may be made, in whole or in part, under the medical assistance program. Defendants also provided or offered an inducement to a person, including a recipient, provider, or public servant, for the purpose of influencing a decision regarding: the use of goods or services provided under the medical assistance program, or the inclusion or exclusion of goods or services available under the medical assistance program. *See* TEX. HUM. RES. CODE § 32.039 (b).

134. Plaintiffs, therefore, seek civil penalties under the TMFPA for each of Defendants' unlawful acts under the TMFPA. Plaintiffs will seek an amount as civil penalties that will be justified and appropriate under the facts and the law.

B. Common Law Fraud

135. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 134 of this Petition.

136. Defendants made representations of material facts, including, but not limited to, the certifications on the VDP applications, to the State of Texas that were false concerning the safety, efficacy, and appropriate use of Seroquel IR and Seroquel XR. Defendants knew such representations were false and/or made the representations recklessly, as a positive assertion, and without knowledge of their truth with the intent that the State of Texas act upon such representations. The State of Texas justifiably relied upon such representations, which caused injury and damages to the State of Texas.

137. Defendants also engaged in common law fraud by nondisclosure by failing to disclose material facts within their knowledge, which they had a duty to disclose, knowing that the Plaintiff State and Texas Medicaid decision makers were not aware of the concealed facts and did not have an equal opportunity to discover the truth. Defendants intended to induce the Plaintiff State and Texas Medicaid decision makers to take action by failing to disclose those facts. Plaintiff State has suffered injury as the result of acting without the knowledge of the undisclosed facts.

138. As a result of Defendant's conduct, Plaintiff State suffered harm and is entitled to recovery under common law fraud, including actual damages and prejudgment interest. Plaintiffs invoke in the broadest sense all relief possible at common law, whether specified in this pleading or not.

C. Defendants Actively Encouraged or Assisted Fiduciaries Of the State to Breach Their Fiduciary Duties

139. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 138 of this Petition.

140. One or more Texas state mental health officials, as employees of the State of Texas, had a fiduciary duty with the State of Texas, including, but not limited to, the duty(ies) of

good faith, fair dealing, loyalty, and/or fidelity owed to the State of Texas and its citizens.

141. Defendants provided substantial assistance to and/or aided, abetted, assisted, induced, or encouraged one or more Texas state mental health officials to breach their fiduciary duty(ies) owed to the State of Texas. Defendants knew that one or more Texas state mental health officials owed fiduciary duty(ies) to the State, yet Defendants executed consulting or other contracts that required services and imposed conditions upon those state employees that were at odds with and at times mutually exclusive to the duty(ies) owed to the State. Defendants also provided inducements to the Texas state mental health official(s), including honoraria. For instance, as referenced in Paragraph 132, *supra*, from 2008 to present Defendants paid over $465,000 in honoraria to two state employees, as part of Defendants' Seroquel Franchise marketing efforts. The contracts, inducements, and other arrangements provided by the Defendants resulted in one or more Texas state mental health officials giving advice and making decisions that advanced the Defendants' financial interests ahead of the State's interests. Further, Defendants knew, or reasonably should have known, that their conduct would cause the Texas state mental health official(s) to breach their fiduciary duty(ies) to the State.

142. Plaintiff State of Texas, and the people and taxpayers of the State of Texas, suffered injury as a proximate result of Defendants' wrongful act(s).

D. Negligent Misrepresentation

143. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 142 of this Petition.

144. Defendants made misrepresentations to the Plaintiff State of Texas, including, but not limited to, the false certifications on the VDP applications, by and through its Texas state mental health decision makers and other officers and employees, in the course of the Defendants'

business or transactions in which Defendants had pecuniary interests.

145. Defendants supplied information that was false for the guidance of others, and failed to exercise reasonable care or competence in obtaining or communicating the information.

146. Plaintiff State, by and through its state mental health decision makers, officers and employees, justifiably relied on the misrepresentations.

147. Defendants' negligent misrepresentations proximately caused Plaintiff State's injuries, including pecuniary loss.

E. Monies Had and Received

148. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 147 of this Petition.

149. Plaintiff State, unaware of Defendants' wrongdoing and unlawful acts, paid excessive Medicaid reimbursements that would otherwise not have been allowed.

150. Defendants hold money that in equity and good conscience belongs to the Plaintiff State, and retention of those funds by any of Defendants would be inequitable and unjust in this case.

151. Defendants should be required to disgorge to Plaintiff State the revenue wrongfully and unlawfully obtained from Seroquel IR and Seroquel XR sales ultimately reimbursed under the Texas Medicaid program.

152. The State demands that judgment be entered against Defendants in an undetermined amount for unjust enrichment, restitution of monies gained by the Defendants, interest and costs of suit, including attorney's fees and all such other relief at law and equity to which the State of Texas is entitled.

153. By reason of the overpayments described above, the State of Texas is entitled to

damages in an amount to be determined at trial exclusive of interest and costs.

F. Promissory Estoppel

154. Plaintiffs re-allege and reincorporate by reference as set forth herein the allegations contained in Paragraphs 1 through 153 of this Petition.

155. Defendants entered into a contractual promise with the State during the VDP application process. During this process, Defendants certified their products' compliance with federal and state laws. Defendants additionally agreed to update the State as to any changes, *inter alia*, in product status. As a result of this promise, Defendants' products Seroquel IR and Seroquel XR were added to, and/or maintained on, the VDP formulary.

156. The State, through VDP, reasonably and substantially relied on Defendants' promise to its detriment.

157. Defendants could have foreseen the State's reliance on the promise, since Texas State law requires the submission of truthful information during the VDP application process.

158. Injustice can be avoided only by enforcing the Defendants' promise to comply with federal and state laws.

159. By reason of the State's reliance on Defendants' promise, described above, the State of Texas is entitled to damages in an amount to be determined at trial.

IX. REMEDIES FOR COMMON LAW CAUSES OF ACTION

160. As a result of Defendants' conduct, to wit: common law fraud, negligent misrepresentation, wrongfully receiving and retaining funds rightfully belonging to the Plaintiff State of Texas, and promissory estoppel as a claim, Plaintiff State suffered harm as a proximate result of that conduct, and are entitled to recovery including actual damages, prejudgment interest, post-judgment interest, disgorgement, restitution for the value of all payments that the

State has made for Seroquel IR and Seroquel XR prescriptions reimbursed under the Texas Medicaid program, and other legal and equitable relief as the court may determine appropriate. Plaintiffs invoke in the broadest sense all relief possible at common law, whether specified in this pleading or not.

X. STATUTORY INJUNCTION UNDER § 36.051 OF THE ACT

161. The Attorney General has good reason to believe the Defendants are committing, have committed, or are about to commit unlawful acts as defined by the TMFPA. These illegal acts may be enjoined under § 36.051 of the TMFPA.

XI. JURY DEMAND

162. Plaintiffs respectfully request a trial by jury on all claims pursuant to Texas Rules of Civil Procedure 216.

XII. PRAYER

163. Plaintiffs ask that judgment be entered upon trial of this case in favor of the State and the Relators against Defendants to the maximum extent allowed by law.

164. Plaintiffs ask for injunctive relief pursuant to § 36.051 of the TMFPA.

165. The State of Texas asks that it recover from Defendants under all applicable Texas common law principles:

A. its reasonable damages as they may appear at trial;

B. punitive or exemplary damages;

C. forfeiture and disgorgement of Defendants' revenues from Seroquel IR and Seroquel XR sales in Texas in connection with Seroquel IR and Seroquel XR use in the Texas Medicaid population;

D. restitution, under the principle of unjust enrichment, of all proceeds improperly gained by Defendants as a result of Defendants' wrongful acts, via the imposition of a constructive trust on Defendants' revenue from Seroquel IR and Seroquel XR sales in Texas in connection with Seroquel IR and Seroquel XR use in the Texas Medicaid population;

E. prejudgment interest and interest on the judgment; and

F. such other and further relief to which it may show itself entitled, either at law or in equity, exclusive of interest and costs.

166. The State of Texas asks that it recover from Defendants under the TMFPA:

A. restitution of the amount of any payments or the value of any monetary or in-kind benefits provided under the Texas Medicaid program, directly or indirectly, as a result of Defendants' unlawful acts;

B. two times the amount of any payments or the value of any monetary or in-kind benefits provided under the Medicaid program, directly or indirectly, as a result of Defendants' unlawful acts;

C. civil penalties in an amount not less than $1,000 or more than $10,000 for each unlawful act committed by Defendants before May 4, 2007; in an amount not less than $5,000 or more than $10,000 for each unlawful act committed by Defendants on or after May 4, 2007 and prior to September 1, 2011; and in an amount not less than $5,500 or more than $11,000 for each unlawful act committed by Defendants on or after September 1, 2011.

D. prejudgment interest;

E. expenses, costs, and attorneys' fees; and

F. post-judgment interest at the legal rate.

167. Plaintiffs seek monetary relief in excess of $1,000,000.

168. The Relators asks that they be awarded:

A. expenses, costs and attorneys' fees;

B. Relator's share as provided by the TMFPA; and

C. Such other and further relief to which Relators may show themselves entitled, either at law or in equity.

Respectfully submitted,

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Washington DC 20037

COUNSEL FOR PLAINTIFF/RELATOR TRACY MIKSELL-BRANCH

CERTIFICATE OF SERVICE

I certify a true and correct copy of the foregoing Plaintiffs' Second Amended Petition has been sent via **electronic mail** on November 14, 2014 to:

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Counsel for Plaintiff/Relator Allison Zayas

Michael Garemko

ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

November 14, 2014

Via Electronic Filing
Ms. Amalia Rodriguez-Mendoza
Travis County District Clerk
1000 Guadalupe, Room 302
Austin, Texas 78701

Re: *The State of Texas ex rel. Allison Zayas and Tracy Miksell-Branch v. AstraZeneca, L.P. and AstraZeneca Pharmaceuticals, L.P.*; Cause No. D-1-GN-13-003530, 353rd District Court, Travis County, Texas.

Dear Ms. Rodriguez-Mendoza:

This letter will serve as a formal request for preparation of an original and one copy of each of the Citations for the defendants listed below in the above-referenced cause number:

1. AstraZeneca, L.P.
c/o Registered Agent
C T Corporation System
1999 Bryan Street, Suite 900
Dallas, Texas 75201-3136

2. AstraZeneca Pharmaceuticals, L.P.
c/o Registered Agent
C T Corporation System
1999 Bryan Street, Suite 900
Dallas, Texas 75201-3136

Our office will be serving the citations by private process. Please send them via electronic mail to my legal assistant Jennifer Rowell at jennifer.rowell@texasattorneygeneral.gov.

If you have any questions, please do not hesitate to call me at the number listed below or my legal assistant. Thank you for your cooperation in this matter.

Sincerely,

Eugenia L. Krieg
Assistant Attorney General
Civil Medicaid Fraud Division
(512) 936-1937
(512) 499-0712 [Fax]

11/20/2014 1:46:47 PM
Amalia Rodriguez-Mendoza
District Clerk
Travis County
D-1-GN-13-003530

CAUSE NO. D-1-GN-13-003530

THE STATE OF TEXAS, *ex rel.* ALLISON ZAYAS and TRACY MIKSELL-BRANCH,	§	IN THE DISTRICT COURT
Plaintiffs,	§	353d JUDICIAL DISTRICT
v.	§	
ASTRAZENECA, L.P., and ASTRAZENECA PHARMACEUTICALS, L.P.	§	TRAVIS COUNTY, TEXAS
Defendants.	§	

PLAINTIFFS' MOTION TO RETAIN AND MEMORANDUM OF FACTS AND LAW IN SUPPORT OF MOTION TO RETAIN

I. Motion to Retain

For the reasons specified herein, the State of Texas and the relators, Allison Zayas and Tracy Miksell-Branch, respectfully move: (1) to retain this action; and (2) to except this action from referral to Alternative Dispute Resolution, pending further orders of the court.

II. Memorandum of Facts and Law Supporting Retention

This is an enforcement action under the Texas Medicaid Fraud Prevention Act, TEX. HUM. RES. CODE ANN. Ch. 36.001, *et seq*. On October 10, 2013, it was filed under seal by the relator, Allison Zayas, as required by the statute, and was served upon the Attorney General but not upon the Defendants, all in compliance with the statute. TEX. HUM. RES. CODE ANN. § 36.102. On September 30, 2014, this case was consolidated and merged for all purposes with Cause Number D-1-GN-14-000792, entitled *State of Texas ex rel. Tracy Miksell-Branch v. AstraZeneca, L.P., et al.*

The State of Texas diligently conducted a thorough, statutorily-authorized investigation of the claims underlying the consolidated action while it was under seal. After reviewing millions of pages of documents and conducting dozens of witness interviews, the State ultimately concluded that the alleged claims had merit. Accordingly, on October 1, 2014, the State of Texas exercised its statutory right to intervene in the consolidated action. On October 8, 2014, the court lifted the seal on the consolidated action and permitted service of process on all Defendants. On November 14, 2014, Plaintiffs filed their Second Amended Petition, which non-suited two previously-named Defendants, pursuant to an agreement with the remaining Defendants. Defendants' counsel agreed to accept service of the Second Amended Petition and was served with that petition on November 18, 2014. Defendants have not yet filed an answer, but are still well within the period allowed to file a responsive pleading.

The State, therefore, promptly pursued this action after the court lifted the seal and permitted service of the Defendants. Accordingly, the State moves to retain this consolidated action. The State moves also to except this action from referral to Alternative Dispute Resolution ("ADR"). Due to the unique nature of this action, and due to its current status (Defendants have not yet answered), it would be premature, inconsistent with the statute under which the action is brought, and contrary to the public interest to require the commencement of ADR procedures at this time.

Respectfully submitted,

GREG ABBOTT
Attorney General of Texas

DANIEL T. HODGE
First Assistant Attorney General

JOHN SCOTT
Deputy Attorney General for Civil Litigation

RAYMOND C. WINTER
Chief, Civil Medicaid Fraud Division

CYNTHIA O'KEEFFE
Deputy Chief, Civil Medicaid Fraud Division

EUGENIA LA FONTAINE KRIEG
State Bar No. 24062830
(512) 936-1937 direct dial

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Washington DC 20037

COUNSEL FOR PLAINTIFF/RELATOR
TRACY MIKSELL-BRANCH

CERTIFICATE OF SERVICE

I certify a true and correct copy of the foregoing Plaintiffs' Motion to Retain and Memorandum of Facts and Law in Support of Motion to Retain has been sent via electronic mail on November 20, 2014 to:

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David Cohen (Bar No. 04508100)
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Counsel for Plaintiff/Relator Allison Zayas

Jonathan Bonilla

CAUSE NO. D-1-GN-13-003530

THE STATE OF TEXAS, *ex rel.* **ALLISON ZAYAS and TRACY MIKSELL-BRANCH,**	§	**IN THE DISTRICT COURT**
Plaintiffs,	§	**353d JUDICIAL DISTRICT**
v.	§	
ASTRAZENECA, L.P., and ASTRAZENECA PHARMACEUTICALS, L.P.	§	**TRAVIS COUNTY, TEXAS**
Defendants.	§	

ORDER GRANING MOTION TO RETAIN

CAME ON THIS DAY to be heard in the above-numbered and styled cause Plaintiffs' Motion to Retain. The Court, having considered said Motion finds it to be well taken and rules that it should be GRANTED in all respects. It is therefore:

ORDERED that Plaintiffs' Motion to Retain be, and is in all things GRANTED.

IT IS FURTHER ORDERED that this cause is excused from referral to Alternative Dispute Resolution pending further order of the Court.

SIGNED this _____ day of November, 2014.

_____
JUDGE PRESIDING

Arrow

CT

November 11, 2014

Travis County District Court
PO Box 1748,
Austin, TX 78767

Re: State of Texas, Pltf. vs. Sealed, Dft. // To: Astrazeneca Biopharmaceuticals Inc

Case No. D1GN13003530

Dear Sir/Madam:

Astrazeneca Biopharmaceuticals Inc is not listed on our records or on the records of the State of TX.

CT was unable to forward.

Very truly yours,

C T Corporation System

Log# 526046041

Sent By Regular Mail

cc: Travis County District Court
PO Box 1748,
Austin, TX 78767

(Returned To)

Travis County District Court
PO Box 1748,
Austin, TX 78767

NOTICE OF COURT SETTING

IN THE DISTRICT COURTS OF TRAVIS COUNTY, TEXAS

FOR CAUSE NO. D-1-GN-13-003530

STATE OF TEXAS
VS.
SEALED

THE ABOVE CAUSE WILL BE DISMISSED FOR WANT OF PROSECUTION ON THE COURT'S MOTION ON THE 19th day of December, 2014 AT 1:45 PM IN SAID COURT, UNLESS A MOTION TO RETAIN IS FILED PRIOR TO THAT DATE.

PLEASE READ THE TRAVIS COUNTY LOCAL RULES CHAPTER 8 -- PROCEDURES FOR DISMISSAL FOR WANT OF PROSECUTION

AMALIA RODRIGUEZ-MENDOZA
DISTRICT CLERK
TRAVIS COUNTY, TEXAS

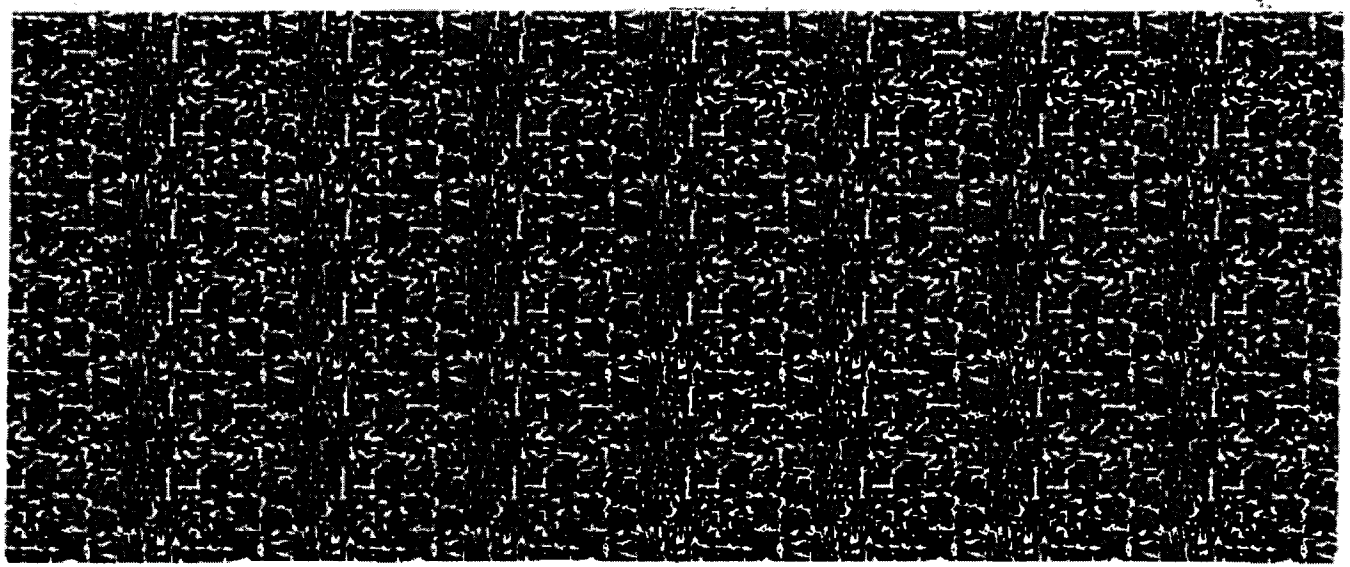
DATED: 11/4/2014

OFFICE OF COURT ADMINISTRATOR
TRAVIS COUNTY COURTHOUSE
P.O BOX 1748
AUSTIN, TX 78767

U.S. POSTAGE PITNEY
ZIP 78701 $ 000.
02 1W
0001376968 NOV. 07

ASTRAZENECA BIOPHARMACCUTICALS INC
BY SERVING THROUGH ITS REGISTERED AGENT
CT CORPORATION SYSTEM
1999 BRYAN STREET, SUITE 900
DALLAS TX 752013136

75201$3140 C005



REMOVE SIDE EDGES FIRST
THEN FOLD AND TEAR THIS STUB ALONG PERFORATION

CAUSE NO. D-1-GN-13-003530

THE STATE OF TEXAS, *ex rel.* **ALLISON ZAYAS and TRACY MIKSELL-BRANCH,**	§	**IN THE DISTRICT COURT**
Plaintiffs,	§	**353d JUDICIAL DISTRICT**
v.	§	
ASTRAZENECA, L.P., and ASTRAZENECA PHARMACEUTICALS, L.P.	§	**TRAVIS COUNTY, TEXAS**
Defendants.	§	

ORDER GRANING MOTION TO RETAIN

CAME ON THIS DAY to be heard in the above-numbered and styled cause Plaintiffs' Motion to Retain. The Court, having considered said Motion finds it to be well taken and rules that it should be GRANTED in all respects. It is therefore:

ORDERED that Plaintiffs' Motion to Retain be, and is in all things GRANTED.

IT IS FURTHER ORDERED that this cause is excused from referral to Alternative Dispute Resolution pending further order of the Court.

SIGNED this 2nd day of ~~November~~ December, 2014.

JUDGE PRESIDING

ORDER TO RETAIN

ENTERED

CAUSE NO. D-1-GN-13-003530

STATE OF TEXAS *ex rel.* [UNDER SEAL]	§	IN THE DISTRICT COURT
Plaintiffs,	§	
v.	§	353RD JUDICIAL DISTRICT
[UNDER SEAL]	§	
Defendants.	§	TRAVIS COUNTY, TEXAS

STATE OF TEXAS' NOTICE OF INTERVENTION

Filed in The District Court
of Travis County, Texas
OCT 01 2014
At 3:06p M.
Amalia Rodriguez-Mendoza, Clerk

JONATHAN D. BONILLA
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Austin, Texas 78711-2548
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ATTORNEY FOR THE STATE OF TEXAS

1 Envelope Sent to File Room. RT 12-12-14

CAUSE NO. D-1-GN-13-003530

STATE OF TEXAS *ex rel.* [UNDER SEAL]	§	IN THE DISTRICT COURT
Plaintiffs,	§	
v.	§	353RD JUDICIAL DISTRICT
[UNDER SEAL]	§	
Defendants.	§	TRAVIS COUNTY, TEXAS

ORDER GRANTING MOTION TO EXTEND SEAL AND TIME FOR THE STATE TO CONSIDER INTERVENTION

1 Envelope Sent to File Room. RT 12-12-14

[redacted]

CAUSE NO. D-1-GN-13-003530

STATE OF TEXAS *ex rel.* [UNDER SEAL]	§	IN THE DISTRICT COURT
Plaintiffs,	§	
v.	§	353RD JUDICIAL DISTRICT
[UNDER SEAL]	§	
Defendants.	§	TRAVIS COUNTY, TEXAS

MOTION TO EXTEND SEAL AND TIME FOR THE STATE TO CONSIDER INTERVENTION

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ATTORNEY FOR THE STATE OF TEXAS

1 Envelope Sent to File Room (RT) 12-12-14

AGREED:

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Assistant Attorney General
Attorney for the State of Texas

James Pepper (By Permission)
JAMES J. PEPPER
Attorney for Plaintiff/Relator Allison Zayas

W. Scott Simmer (By permission)
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Attorney for Plaintiff/Relator Tracy Miksell-Branch